EXHIBIT H

At Your Service

Search

Home > Results

Roche

Protocol Registry | Trial Results | IFPMA Trial Portal | Background | Links

About This Database

This database will be populated with information on Roche clinical trial results. Results information will be posted in a staged approach.

For more information

Common Questions

What are the differences between clinical trial phases?

Why has Roche decided to launch a registry and database at this time?

More FAQs

Glossary of Terms

Phase Definitions

Field Definitions

Roche Clinical Trial Global Policy

Site provided by THOMSON CENTERWATCH

Trial Results Search

Clinical Trial Result Information

Protocol number
BA16286

Title of Study
A Study of Subcutaneous (sc) RO0503821 in Dialysis Patients With Chronic Renal Anemia

Sponsor
Hoffmann-La Roche Ltd

Company division
Pharmaceutical

Product name
RO0503821

Therapeutic area
Anemia

Clinical study summary
This trial does not yet have clinical trial results posted on this website. All trial results will be posted within one year of approval or one year after trial completion, unless the release of information is restricted due to journal publication timing or pending regulatory filing. For further information on the timing of posting clinical trial results please consult the Roche policy for posting information on this website.

Phase of development
II

Date of report
To be Published

Click here for the protocol registry listing of this trial.

Trial Results updated: March 27, 2006 at 10:37:32 AM

This registry will serve as a global repository for information on ongoing Phase II through Phase IV clinical studies.

For more information

Common Questions

Why participate in a study?

Who is eligible to participate?

What are the differences between clinical trial phases?

More FAQs

About Clinical Trials

Glossary of Terms

Phase Definitions

Field Definitions

Roche Clinical Trial Global Policy

Site provided by THOMSON CenterWatch

Clinical Trial Search

Trial information

A Study of Subcutaneous (sc) RO0503821 in Dialysis Patients With Chronic Renal Anemia

Status: *No longer recruiting*

Protocol number: BA16286

Sponsor: Hoffmann-La Roche Ltd

Company division: Pharmaceutical

Official Scientific Title: A randomized, open-label study of dose conversion factors for maintenance subcutaneous RO050382 in dialysis patients with chronic renal anemia

Brief summary: This study will determine the appropriate dose and frequency of administration of sc RO0503821 maintenance therapy in dialysis patients with chronic renal anemia who were previously receiving sc epoetin alfa or beta. The anticipated time on study treatment is 3-12 months and the target sample size is 100-500 individuals.

Study phase: II

Study type: Interventional; Treatment; Randomized; Open Label; Active; Parallel; Safety/Efficacy study

Condition: Anemia

Intervention type: Drug

Intervention name: RO0503821

Primary outcome: Efficacy: Change in hemoglobin from baseline over time under constant dosing regimen

Key secondary outcomes: Efficacy: Change in hematocrit from baseline over time under constant dosing regimen Safety: Vital signs, adverse events, laboratory values

Inclusion criteria:

- adult patients >=18 years of age;
- chronic renal anemia;
- on dialysis (hemodialysis or peritoneal dialysis) therapy for at least 3 months;
- receiving sc epoetin alfa or beta for at least 3 months prior to the run-in period.

Exclusion criteria:

- women who are pregnant, breastfeeding or using unreliable birth control methods;
- use of any investigational drug within 30 days preceding the run-in phase, or during the run-in or study treatment period.

Gender: Males or Females

Age limits: Min: 18 Years Max: N/A (No limit)

Accepts healthy volunteers: No

Anticipated start date: October, 2001

Trial registration date: 05/23/2005

Date last updated: 3/27/2006

Link to trial result

This trial was conducted at the following locations:

Germany

- Berlin
- Mannheim
- Stuttgart
- Villingen-Schwenningen
- Wiesloch

Italy

- Bari
- Bergamo
- Lecco
- Lodi
- Milano
- Modena
- Pavia
- Vicenza

Spain

- Barcelona
- Madrid
- Malaga
- Santander

United States

- Los Angeles, CA
- San Jose, CA
- Indianapolis , IN
- Boston, MA
- Cleveland, OH
- Houston, TX
- Morgantown, WV

To contact Roche for more information on this trial please complete the email form below. Treatment decisions and/or suitability for a specific trial are decisions only your healthcare provider can make. Therefore, extensive medical information need not be include in your query. To guarantee timely processing of your query, please be concise.If you are patient interested in any of the studies, please have your healthcare provider contact us via this website, and they will be provided with the relevant clinical trial information.

Country* Please Select

Subject* Please Select

Your message

Last Name*

First Name*

Address

Telephone

E-mail*

your email address is needed for us to reply

Are you a:* Please Select

Send Clear Form

About This Database

This database will be populated with information on Roche clinical trial results. Results information will be posted in a staged approach.

For more information

Common Questions

What are the differences between clinical trial phases?

Why has Roche decided to launch a registry and database at this time?

More FAQs

Glossary of Terms

Phase Definitions

Field Definitions

Roche Clinical Trial Global Policy

Site provided by: THOMSON CENTERWATCH

Trial Results Search

Clinical Trial Result Information

Protocol number
BA16736

Title of Study
A Study of RO0503821 for the Treatment of Anemia in Dialysis Patients

Sponsor
Hoffmann-La Roche Ltd

Company division
Pharmaceutical

Product name
RO0503821

Therapeutic area
Anemia

Clinical study summary
This trial does not yet have clinical trial results posted on this website. All trial results will be posted within one year of approval or one year after trial completion, unless the release of information is restricted due to journal publication timing or pending regulatory filing. For further information on the timing of posting clinical trial results please consult the Roche policy for posting information on this website.

Phase of development
III

Date of report
To be Published

Click here for the protocol registry listing of this trial.

Trial Results updated: March 27, 2006 at 10:37:32 AM

Clinical Trial Search

Trial information

A Study of RO0503821 for the Treatment of Anemia in Dialysis Patients

Status: *No longer recruiting*

Protocol number: BA16736

Sponsor: Hoffmann-La Roche

Company division: Pharmaceutical

Official Scientific Title: A randomized, open-label study of the effect of intravenous RO0503821 on hemoglobin level/correction in dialysis patients with chronic kidney disease

Brief summary: This study will assess the efficacy and safety of RO0503821 given intravenously in the treatment of renal anemia in chronic kidney disease patients on dialysis who are not currently receiving epoetin or any other erythropoietic substance. The anticipated time on study treatment is 1-2 years and the target sample size is 100-500 individuals.

Study phase: III

Study type: Interventional; Treatment; Randomized; Open Label; Active; Parallel; Safety/Efficacy study

Condition: Anemia

Intervention type: Drug

Intervention name: RO0503821

Primary outcome: Efficacy: Hemoglobin response rate during the first 24 weeks

Key secondary outcomes: Efficacy: Hb over time, time to target Hb response, incidence of RBC transfusions Safety: Vital signs, ECG, AEs, laboratory values

Inclusion criteria:

- adult patients >=18 years of age;
- chronic renal anemia;
- dialysis therapy for at least 2 weeks before screening.

Exclusion criteria:

- women who are pregnant, breastfeeding or using unreliable birth control methods;
- administration of any investigational drug within 4 weeks before screening.

Gender: Males or Females

Age limits: Min: 18 Years Max: N/A (No limit)

Accepts healthy volunteers: No

Anticipated start date: February, 2004

Trial registration date: 05/23/2005

Date last updated: 3/27/2006

Link to trial result

This trial was conducted at the following locations:

Brazil

- Curitiba
- Ribeirão Preto
- Sao Paulo

Canada

- Calgary, AB
- Vancouver, BC
- Winnipeg, MB
- St. John'S
- Kingston, ON
- London, ON
- Scarborough, ON
- Toronto, ON
- Montreal, QC
- Saskatoon, SK

Czech Republic

- Liberec
- Praha
- Usti Nad Labem

Greece

- Alexandroupolis
- Larissa
- Nikea
- Thessaloniki

New Zealand

- Christchurch

Norway

- Bergen
- Oslo

Poland

- Gdansk
- Gdynia
- Krakow
- Lodz
- Poznan
- Szczecin
- Wolomin
- Wroclaw

Russian Federation

- Moscow
- St. Petersburg

South Africa

- Cape Town
- Johannesburg
- Soweto

Spain

- Bilbao
- Santander
- Valencia

Sweden

- Karlstad

Switzerland

- Aarau
- Lausanne

Thailand

- Bangkok
- Chiang Mai
- Chonburi

United States

- Montgomery, AL
- Davis, CA
- Lakewood, CO
- Atlanta, GA
- Augusta, GA
- New Orleans, LA
- Boston, MA
- Springfield, MA
- Detroit, MI
- Mineola, NY
- New York, NY
- Toledo, OH
- Aguadilla, PR
- Mayaguez, PR
- Houston, TX
- Burlington, VT
- Norfolk , VA

To contact Roche for more information on this trial please complete the email form below. Treatment decisions and/or suitability for a specific trial are decisions only your healthcare provider can make. Therefore, extensive medical information need not be include in your query. To guarantee timely processing of your query, please be concise.If you are patient interested in any of the studies, please have your healthcare provider contact us via this website, and they will be provided with the relevant clinical trial information.

Country* Please Select

Subject* Please Select

Your message

Last Name*

First Name*

Address

Telephone

E-mail*

your email address is needed for us to reply

Are you a:* Please Select

Send Clear Form

About This Database

This database will be populated with information on Roche clinical trial results. Results information will be posted in a staged approach.

For more information

Common Questions

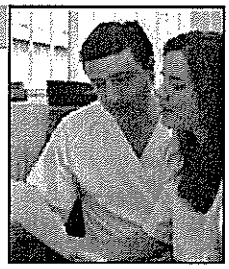
What are the differences between clinical trial phases?

Why has Roche decided to launch a registry and database at this time?

More FAQs
Glossary of Terms
Phase Definitions
Field Definitions
Roche Clinical Trial Global Policy

Site provided by: THOMSON CENTRIWATCH

Trial Results Search



Clinical Trial Result Information

Protocol number
BA16738

Title of Study
A Study of RO0503821 in the Treatment of Anemia in Patients With Chronic Kidney Disease Not on Dialysis

Sponsor
Hoffmann-La Roche Ltd

Company division
Pharmaceutical

Product name
RO0503821

Therapeutic area
Anemia

Clinical study summary
This trial does not yet have clinical trial results posted on this website. All trial results will be posted within one year of approval or one year after trial completion, unless the release of information is restricted due to journal publication timing or pending regulatory filing. For further information on the timing of posting clinical trial results please consult the Roche policy for posting information on this website.

Phase of development
III

Date of report
To be Published

Click here for the protocol registry listing of this trial.

Trial Results updated: March 27, 2006 at 10:37:32 AM

At Your Service

Search

About This Registry

This registry will serve as a global repository for information on ongoing Phase II through Phase IV clinical studies.

For more information

Common Questions

Why participate in a study?

Who is eligible to participate?

What are the differences between clinical trial phases?

More FAQs

About Clinical Trials

Glossary of Terms

Phase Definitions

Field Definitions

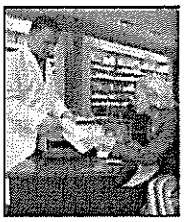
Roche Clinical Trial Global Policy

Site provided by: THOMSON CENTRAWATCH

Home > Registry

Protocol Registry | Trial Results | IFPMA Trial Portal | Background | Links

Clinical Trial Search



Trial information

A Study of RO0503821 in the Treatment of Anemia in Patients With Chronic Kidney Disease Not on Dialysis

Status: *No longer recruiting*

Protocol number: BA16738

Sponsor: Hoffmann-La Roche

Company division: Pharmaceutical

Official Scientific Title: A randomized, open-label study of the effect of subcutaneous RO0503821 on hemoglobin level/correction in non-dialysis patients with chronic kidney disease

Brief summary: This study will assess the efficacy and safety of subcutaneous RO0503821 in the treatment of renal anemia in patients with chronic kidney disease who are not on dialysis and not receiving epoetin or any other erythropoietic substance. The anticipated time on study treatment is 1-2 years and the target sample size is 100-500 individuals.

Study phase: III

Study type: Interventional; Treatment; Randomized; Open Label; Active; Parallel; Safety/Efficacy study

Condition: Anemia

Intervention type: Drug

Intervention name: RO0503821

Primary outcome: Efficacy: Hemoglobin response rate during the first 28 weeks

Key secondary outcomes: Efficacy: Hb concentration over time, time to target Hb response, incidence of RBC transfusions Safety: Vital signs, ECG, adverse events, laboratory values

Inclusion criteria:

- adult patients >=18 years of age;
- chronic kidney disease;
- anemia;
- not on dialysis therapy;
- not receiving epoetin.

Exclusion criteria:

- women who are pregnant, breastfeeding or using unreliable birth control methods;
- administration of another investigational drug within 4 weeks before screening, or during the study period.

Gender: Males or Females

Age limits: Min: 18 Years Max: N/A (No limit)

Accepts healthy volunteers: No

Anticipated start date: June, 2004

Trial registration date: 05/23/2005

Date last updated: 3/27/2006

Link to trial result

This trial was conducted at the following locations:

Australia

- Camperdown
- Clayton
- Parkville
- Perth
- Sydney

Belgium

- Antwerpen
- Leuven

Canada

- Calgary, AB
- Edmonton, AB
- Kamloops, BC
- New Westminster, BC
- Vancouver, BC
- Winnipeg, MB
- St. John'S
- Kitchener, ON
- London, ON
- Scarborough, ON
- Toronto, ON
- Montreal, QC
- Saskatoon, SK

France

- Amiens
- Angers
- Besancon
- Chartres
- Colmar
- Lille
- Lyon
- Nantes
- Paris
- Perpignan
- Toulouse
- Vandoeuvre-Lès-Nancy

Germany

- Aschaffenburg
- Berlin
- Bonn
- Dortmund
- Duesseldorf
- Tuebingen

Greece

- Alexandroupolis
- Athens
- Ioannina
- Piraeus

- Thessaloniki

Italy

- Cagliari
- Cuneo
- Genova
- Lecco
- Lodi
- Modena
- Napoli
- Padova
- Parma
- Pavia
- Prato
- Reggio Calabria
- Roma

Netherlands

- Amersfoort
- Heerlen

Spain

- Almeria
- Barcelona
- Lerida
- Madrid
- Palma de Mallorca
- Valencia

Sweden

- Boras
- Umea

United Kingdom

- Birmingham
- Carshalton
- Leicester
- London

United States

- Scottsdale, AZ
- Los Angeles, CA
- Mather, CA
- Stanford, CA
- Stamford, CT
- Bay Pines, FL
- Ocala, FL
- Atlanta, GA
- Evanston, IL
- Shreveport, LA
- Boston, MA
- Detroit, MI
- Flushing, NY
- Cincinnati, OH
- Portland, OR
- Allentown, PA
- San Juan, PR
- Columbia, SC
- Nashville, TN
- Austin, TX
- Dallas, TX
- Houston, TX
- Burlington, VT
- Salem, VA
- Morgantown, WV

To contact Roche for more information on this trial please complete the email form below. Treatment decisions and/or suitability for a specific trial are decisions only your healthcare provider can make. Therefore, extensive medical information need not be include in your query. To guarantee timely processing of your query, please be concise.If you are patient interested in any of the studies, please have your healthcare provider contact us via this website, and they will be provided with the relevant clinical trial information.

Country* Please Select

Subject* Please Select

Your message

Last Name*

First Name*

Address

Telephone

E-mail*

your email address is needed for us to reply

Are you a:* Please Select

Send Clear Form

About This Database

This database will be populated with information on Roche clinical trial results. Results information will be posted in a staged approach.

For more information

Common Questions

What are the differences between clinical trial phases?

Why has Roche decided to launch a registry and database at this time?

More FAQs

Glossary of Terms

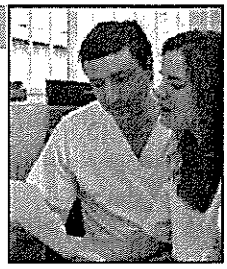
Phase Definitions

Field Definitions

Roche Clinical Trial Global Policy

Site provided by: THOMSON CENTERWATCH

Trial Results Search



Clinical Trial Result Information

Protocol number
BA16739

Title of Study
A Study of Intravenous RO0503821 for the Treatment of Anemia in Dialysis Patients

Sponsor
Hoffmann-La Roche Ltd

Company division
Pharmaceutical

Product name
RO0503821

Therapeutic area
Anemia

Clinical study summary
This trial does not yet have clinical trial results posted on this website. All trial results will be posted within one year of approval or one year after trial completion, unless the release of information is restricted due to journal publication timing or pending regulatory filing. For further information on the timing of posting clinical trial results please consult the Roche policy for posting information on this website.

Phase of development
III

Date of report
To be Published

Click here for the protocol registry listing of this trial.

Trial Results updated: March 27, 2006 at 10:37:32 AM

This registry will serve as a global repository for information on ongoing Phase II through Phase IV clinical studies.

For more information

Common Questions

Why participate in a study?

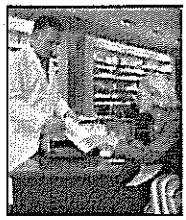
Who is eligible to participate?

What are the differences between clinical trial phases?

More FAQs
About Clinical Trials
Glossary of Terms
Phase Definitions
Field Definitions
Roche Clinical Trial Global Policy

Site provided by: THOMSON CENTRIWATCH

Clinical Trial Search



Trial information

A Study of Intravenous RO0503821 for the Treatment of Anemia in Dialysis Patients

Status: *No longer recruiting*

Protocol number: BA16739

Sponsor: Hoffmann-La Roche

Company division: Pharmaceutical

Official Scientific Title: A randomized, open-label study of the effect of maintenance intravenous RO0503821 on hemoglobin level/correction in patients with chronic kidney disease

Brief summary: This study will assess the efficacy and safety of intravenous RO0503821, given as maintenance treatment for renal anemia in chronic kidney disease patients on dialysis who were previously receiving iv epoetin. The anticipated time on study treatment is 1-2 years and the target sample size is 100-500 individuals.

Study phase: III

Study type: Interventional; Treatment; Randomized; Open Label; Active; Parallel; Safety/Efficacy study

Condition: Anemia

Intervention type: Drug

Intervention name: RO0503821

Primary outcome: Efficacy: Change in hemoglobin concentration between the baseline and evaluation periods

Key secondary outcomes: Efficacy: Patients within 1 g/dL of their average baseline Hb concentration, RBC transfusions Safety: Vital signs, AEs, laboratory values

Inclusion criteria:

- adult patients >=18 years of age;
- chronic renal anemia;
- on dialysis therapy for at least 12 weeks before screening;
- receiving IV epoetin for at least 8 weeks before screening.

Exclusion criteria:

- women who are pregnant, breastfeeding or using unreliable birth control methods;
- administration of another investigational drug within 4 weeks before screening, or during the study period.

Gender: Males or Females

Age limits: Min: 18 Years Max: N/A (No limit)

Accepts healthy volunteers: No

Anticipated start date: February, 2004

Trial registration date: 05/23/2005

Date last updated: 3/27/2006

Link to trial result

This trial was conducted at the following locations:

Canada

- St. John'S
- Kingston, ON
- London, ON
- Mississauga, ON
- Scarborough, ON
- Toronto, ON
- Weston, ON
- Montreal, QC
- Saskatoon, SK

France

- Aubervilliers
- Bordeaux
- Grenoble
- Paris
- Toulouse

Germany

- Dortmund
- Muenchen
- Nuernberg
- Stuttgart
- Wiesbaden
- Wiesloch
- Wuppertal

Italy

- Como
- Lecco
- Lodi
- Milano
- Pavia

Norway

- Bergen
- Levanger
- Lillehammer
- Trondheim

Spain

- Barcelona
- La Coruna
- Madrid
- Malaga
- Sevilla

Switzerland

- Lausanne

United States

- Birmingham, AL

- Mobile, AL
- Montgomery, AL
- Encino, CA
- Irvine, CA
- Los Angeles, CA
- Monterey Park, CA
- Orange, CA
- Riverside, CA
- Sacramento, CA
- San Diego , CA
- San Francisco, CA
- San Jose, CA
- San Pablo, CA
- Colorado Springs, CO
- Denver, CO
- Lakewood, CO
- Coral Gables, FL
- Ocala, FL
- Pembroke Pines, FL
- Atlanta, GA
- Augusta, GA
- Chicago, IL
- Maywood, IL
- Louisville, KY
- Covington, LA
- Baltimore, MD
- Boston, MA
- Springfield, MA
- Detroit, MI
- Brooklyn Center, MN
- Paterson, NJ
- Albuquerque, NM
- Bronx, NY
- Brooklyn, NY
- Great Neck, NY
- Mineola, NY
- New York, NY
- Stony Brook, NY
- Chapel Hill, NC
- Raleigh, NC
- Winston-Salem, NC
- Cincinnati, OH
- Toledo, OH
- Portland, OR
- Erie, PA
- Philadelphia, PA
- Pittsburgh, PA
- Orangeburg, SC
- Chattanooga, TN
- Memphis , TN
- Nashville, TN
- Austin, TX
- Houston, TX
- San Antonio, TX
- Burlington, VT
- Fairfax , VA
- Richmond, VA
- Marshfield, WI

To contact Roche for more information on this trial please complete the email form below. Treatment decisions and/or suitability for a specific trial are decisions only your healthcare provider can make. Therefore, extensive medical information need not be include in your query. To guarantee timely processing of your query, please be concise.If you are patient interested in any of the studies, please have your healthcare provider contact us via this website, and they will be provided with the relevant clinical trial information.

Country* Please Select

Subject* Please Select

Your message

Last Name*

First Name*

Address

Telephone

E-mail*

your email address is needed for us to reply

Are you a:* Please Select

Send Clear Form

About This Database

This database will be populated with information on Roche clinical trial results. Results information will be posted in a staged approach.

For more information

Common Questions

What are the differences between clinical trial phases?

Why has Roche decided to launch a registry and database at this time?

More FAQs

Glossary of Terms

Phase Definitions

Field Definitions

Roche Clinical Trial Global Policy

Site provided by THOMSON CENTERWATCH

Trial Results Search

Clinical Trial Result Information

Protocol number
BA16740

Title of Study
A Study of Subcutaneous RO0503821 for the Treatment of Anemia in Dialysis Patients

Sponsor
Hoffmann-La Roche Ltd

Company division
Pharmaceutical

Product name
RO0503821

Therapeutic area
Anemia

Clinical study summary
This trial does not yet have clinical trial results posted on this website. All trial results will be posted within one year of approval or one year after trial completion, unless the release of information is restricted due to journal publication timing or pending regulatory filing. For further information on the timing of posting clinical trial results please consult the Roche policy for posting information on this website.

Phase of development
III

Date of report
To be Published

Click here for the protocol registry listing of this trial.

Trial Results updated: March 27, 2006 at 10:37:32 AM

This registry will serve as a global repository for information on ongoing Phase II through Phase IV clinical studies.

For more information

Common Questions

Why participate in a study?

Who is eligible to participate?

What are the differences between clinical trial phases?

More FAQs

About Clinical Trials

Glossary of Terms

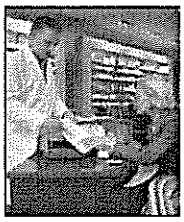
Phase Definitions

Field Definitions

Roche Clinical Trial Global Policy

Site provided by: THOMSON CENTRAWatch

Clinical Trial Search



Trial information

A Study of Subcutaneous RO0503821 for the Treatment of Anemia in Dialysis Patients

Status: *No longer recruiting*

Protocol number: BA16740

Sponsor: Hoffmann-La Roche

Company division: Pharmaceutical

Official Scientific Title: A randomized, open-label study of the effect of maintenance subcutaneous RO0503821 on hemoglobin levels in dialysis patients with chronic kidney disease

Brief summary: This study will assess the efficacy and safety of subcutaneous (sc) RO0503821 given as maintenance treatment for renal anemia in chronic kidney disease patients on dialysis who were previously receiving sc epoetin. The anticipated time on study treatment is 1-2 years and the target sample size is 100-500 individuals.

Study phase: III

Study type: Interventional; Treatment; Randomized; Open Label; Active; Parallel; Safety/Efficacy study

Condition: Anemia

Intervention type: Drug

Intervention name: RO0503821

Primary outcome: Efficacy: Change in hemoglobin concentration between the baseline and evaluation periods.

Key secondary outcomes: Efficacy: Patients within 1 g/dL of their average baseline Hb concentration, RBC transfusions Safety: Vital signs, AEs, laboratory values.

Inclusion criteria:

- adult patients >=18 years of age;
- chronic renal anemia;
- on dialysis therapy for at least 12 weeks before screening;
- receiving sc epoetin for at least 8 weeks before screening.

Exclusion criteria:

- women who are pregnant, breastfeeding or using unreliable birth control methods;
- administration of another investigational drug within 4 weeks before screening, or during the study period.

Gender: Males or Females

Age limits: Min: 18 Years Max: N/A (No limit)

Accepts healthy volunteers: No

Anticipated start date: March, 2004

Trial registration date: 05/23/2005

Date last updated: 3/27/2006

Link to trial result

This trial was conducted at the following locations:

Belgium

- Bruxelles
- Edegem
- Gent
- Hasselt

Brazil

- Curitiba
- Sao Paulo

Czech Republic

- Brno
- Ostrava
- Plzen

Denmark

- Århus
- Odense

Finland

- Hus
- Tampere
- Turku

France

- Bayonne
- Boulogne
- Cabestany
- Caen
- Limoges
- Nimes
- Pantin
- Poitiers
- Reims
- Saint Etienne
- Saint-Germain-En-Laye
- Thionville
- Tours

Germany

- Bad Hersfeld
- Berlin
- Fulda
- Kaiserslautern

Hungary

- Budapest
- Debrecen
- Miskolc
- Pecs

Italy

- Cremona
- Lecco
- Modena
- Prato
- Venezia
- Venezia Mestre

Mexico

- Cuernavaca
- Mexico City

New Zealand

- Christchurch
- Wellington

Panama

- Panama City

Poland

- Gdansk
- Kielce
- Krakow
- Warszawa
- Wroclaw
- Zielona Gora

South Africa

- Durban

Spain

- Alcorcon
- Barcelona
- Galdakao
- Madrid
- Palma de Mallorca
- Pamplona
- Santiago de Compostela
- Zaragoza

Sweden

- Huddinge
- Karlstad

Taiwan

- Taichung
- Taipei

Thailand

- Bangkok
- Phitsanulok

United Kingdom

- Belfast
- Cambridge
- Dundee
- Exeter
- Leicester
- London

United States

- Hot Springs, AR

- Los Angeles, CA
- Orange, CA
- Riverside, CA
- Sacramento, CA
- San Jose, CA
- Boston, MA
- Springfield, MA
- Detroit, MI
- Brooklyn Center, MN
- Raleigh, NC
- Winston-Salem, NC
- Cincinnati, OH
- Toledo, OH
- Portland, OR
- Ponce, PR
- Dallas, TX
- Houston, TX
- San Antonio, TX
- Morgantown, WV

To contact Roche for more information on this trial please complete the email form below. Treatment decisions and/or suitability for a specific trial are decisions only your healthcare provider can make. Therefore, extensive medical information need not be include in your query. To guarantee timely processing of your query, please be concise.If you are patient interested in any of the studies, please have your healthcare provider contact us via this website, and they will be provided with the relevant clinical trial information.

Country* Please Select

Subject* Please Select

Your message

Last Name*

First Name*

Address

Telephone

E-mail*

your email address is needed for us to reply

Are you a:* Please Select

Send Clear Form

About This Database

This database will be populated with information on Roche clinical trial results. Results information will be posted in a staged approach.

For more information

Common Questions

What are the differences between clinical trial phases?

Why has Roche decided to launch a registry and database at this time?

More FAQs

Glossary of Terms

Phase Definitions

Field Definitions

Roche Clinical Trial Global Policy

Site provided by THOMSON CENTRAINTER

Trial Results Search

Clinical Trial Result Information

Protocol number
BA17284

Title of Study
A Study of Intravenous or Subcutaneous RO0503821 for the Treatment of Anemia in Dialysis Patients

Sponsor
Hoffmann-La Roche Ltd

Company division
Pharmaceutical

Product name
RO0503821

Therapeutic area
Anemia

Clinical study summary
This trial does not yet have clinical trial results posted on this website. All trial results will be posted within one year of approval or one year after trial completion, unless the release of information is restricted due to journal publication timing or pending regulatory filing. For further information on the timing of posting clinical trial results please consult the Roche policy for posting information on this website.

Phase of development
III

Date of report
To be Published

Click here for the protocol registry listing of this trial.

Trial Results updated: March 27, 2006 at 10:37:32 AM

Clinical Trial Search

Trial information

A Study of Intravenous or Subcutaneous RO0503821 for the Treatment of Anemia in Dialysis Patients

Status: *No longer recruiting*

Protocol number: BA17284

Sponsor: Hoffmann-La Roche

Company division: Pharmaceutical

Official Scientific Title: A randomized, open-label study of the effect of maintenance RO0503821 administered with pre-filled syringes on hemoglobin levels in anemic dialysis patients with chronic kidney disease

Brief summary: This study will assess the efficacy and safety of intravenous (iv) or subcutaneous (sc) RO0503821, administered with pre-filled syringes, as maintenance treatment for renal anemia in chronic kidney disease patients on dialysis who were previously receiving iv or sc epoetin. The anticipated time on study treatment is 3-12 months and the target sample size is 100-500 individuals.

Study phase: III

Study type: Interventional; Treatment; Randomized; Open Label; Active; Parallel; Safety/Efficacy study

Condition: Anemia

Intervention type: Drug

Intervention name: RO0503821

Primary outcome: Efficacy: Change in hemoglobin concentration between the baseline and evaluation periods

Key secondary outcomes: Efficacy: Patients within 1 g/dL of their average baseline Hb concentration, RBC transfusions Safety: Vital signs, AEs, laboratory values

Inclusion criteria:

- adult patients >=18 years of age;
- chronic renal anemia;
- on dialysis therapy for at least 12 weeks before screening;
- receiving iv or sc epoetin for at least 8 weeks before screening.

Exclusion criteria:

- women who are pregnant, breastfeeding or using unreliable birth control methods;
- administration of another investigational drug within 4 weeks before screening, or during the study period.

Gender: Males or Females

Age limits: Min: 18 Years Max: N/A (No limit)

Accepts healthy volunteers: No

Anticipated start date: June, 2004

Trial registration date: 05/23/2005

Date last updated: 3/27/2006

Link to trial result

This trial was conducted at the following locations:

Canada

- Ottawa, ON
- Toronto, ON
- Greenfield Park, QC
- Montreal, QC

France

- Aix en Provence
- Chambery
- Hyeres
- Le Kremlin-Bicêtre
- Nantes
- Paris
- Rouen

Germany

- Erlangen
- Muenchen
- Nuernberg

Italy

- Como
- Modena
- Pavia

Poland

- Rzeszow
- Warszawa

Portugal

- Carnaxide
- Porto
- Setubal

Spain

- Alicante
- Badalona
- Leon
- Madrid

Taiwan

- Kaohsiung
- Taichung
- Taipei

Thailand

- Bangkok
- Chonburi

United Kingdom

- Glasgow

- Hertford
- London
- Salford
- Swansea

United States

- Covina, CA
- Los Alamitos, CA
- Los Angeles, CA
- San Diego , CA
- Stamford, CT
- Tampa, FL
- Blue Ridge, GA
- Newnan, GA
- Honolulu, HI
- Evanston, IL
- South Holland, IL
- Baton Rouge, LA
- New Orleans, LA
- Shreveport, LA
- Boston, MA
- Kalamazoo, MI
- Columbus, MS
- Tupelo, MS
- St. Louis, MO
- Hackensack, NJ
- Flushing, NY
- New York, NY
- Orchard Park, NY
- Cleveland, OH
- Oregon City, OR
- Erie, PA
- Lewistown, PA
- Philadelphia, PA
- Ponce, PR
- San Juan, PR
- Columbia, SC
- Memphis , TN
- Charlottesville, VA
- Norfolk , VA

To contact Roche for more information on this trial please complete the email form below. Treatment decisions and/or suitability for a specific trial are decisions only your healthcare provider can make. Therefore, extensive medical information need not be include in your query. To guarantee timely processing of your query, please be concise.If you are patient interested in any of the studies, please have your healthcare provider contact us via this website, and they will be provided with the relevant clinical trial information.

Country* Please Select

Subject* Please Select

Your message

Last Name*

First Name*

Address

Telephone

E-mail*

your email address is needed for us to reply

Are you a:* Please Select

Send Clear Form

At Your Service

Search

Home > Results

Roche

Protocol Registry | Trial Results | IFPMA Trial Portal | Background | Links

About This Database

This database will be populated with information on Roche clinical trial results. Results information will be posted in a staged approach.

For more information

Common Questions

What are the differences between clinical trial phases?

Why has Roche decided to launch a registry and database at this time?

More FAQs

Glossary of Terms

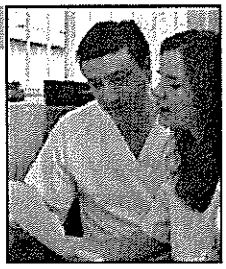
Phase Definitions

Field Definitions

Roche Clinical Trial Global Policy

Site provided by THOMSON CENTERWATCH

Trial Results Search



Clinical Trial Result Information

Protocol number
BH18387

Title of Study
A Study of Intravenous or Subcutaneous RO0503821 in Chronic Kidney Disease Patients With Renal Anemia

Sponsor
Hoffmann-La Roche Ltd

Company division
Pharmaceutical

Product name
RO0503821

Therapeutic area
Anemia

Clinical study summary
This trial does not yet have clinical trial results posted on this website. All trial results will be posted within one year of approval or one year after trial completion, unless the release of information is restricted due to journal publication timing or pending regulatory filing. For further information on the timing of posting clinical trial results please consult the Roche policy for posting information on this website.

Phase of development
III

Date of report
To be Published

Click here for the protocol registry listing of this trial.

Trial Results updated: March 27, 2006 at 10:37:32 AM

Clinical Trial Search

Trial information

A Study of Intravenous or Subcutaneous RO0503821 in Chronic Kidney Disease Patients With Renal Anemia

Status: *No longer recruiting*

Protocol number: BH18387

Sponsor: Hoffmann-La Roche

Company division: Pharmaceutical

Official Scientific Title: An open-label study of the effect of long-term RO0503821 on hemoglobin levels in patients with chronic renal anemia

Brief summary: This study will assess the long term efficacy, safety and tolerability of intravenous (iv) or subcutaneous (sc) RO0503821 in chronic kidney disease patients with renal anemia. The anticipated time on study treatment is 2+ years and the target sample size is 500+ individuals.

Study phase: III

Study type: Interventional; Treatment; Non-Randomized; Open Label; Uncontrolled; Parallel; Safety/Efficacy study

Condition: Anemia

Intervention type: Drug

Intervention name: RO0503821

Primary outcome: Efficacy: Hemoglobin concentrations over time

Key secondary outcomes: Safety: Vital signs, adverse events, laboratory values

Inclusion criteria:

- adult patients >=18 years of age;
- chronic renal anemia;
- currently receiving RO0503821 as part of a clinical study.

Exclusion criteria:

- women who are pregnant, breastfeeding or using unreliable birth control methods;
- administration of another investigational drug planned during the study period.

Gender: Males or Females

Age limits: Min: 18 Years Max: N/A (No limit)

Accepts healthy volunteers: No

Anticipated start date: September, 2004

Trial registration date: 05/23/2005

Date last updated: 3/27/2006

Link to trial result

This trial was conducted at the following locations:

Australia

- Blacktown
- Brisbane
- Clayton
- Gosford
- Parkville
- Perth
- Sydney

Austria

- Graz

Belgium

- Aalst
- Bruxelles
- Edegem
- Gent
- Hasselt
- Leuven
- Liege

Brazil

- Sao Paulo

Canada

- Calgary, AB
- Edmonton, AB
- Kamloops, BC
- New Westminster, BC
- Vancouver, BC
- Winnipeg, MB
- St. John'S
- Halifax, NS
- Kingston, ON
- Kitchener, ON
- London, ON
- Mississauga, ON
- Ottawa, ON
- Scarborough, ON
- Toronto, ON
- Weston, ON
- Greenfield Park, QC
- Montreal, QC
- Saskatoon, SK

Czech Republic

- Brno
- Liberec
- Ostrava
- Plzen
- Praha

Denmark

- Aalborg
- Odense
- Roskilde

Finland

- Hus
- Tampere
- Turku

France

- Amiens
- Aubervilliers
- Bayonne
- Bordeaux
- Boulogne
- Cabestany
- Caen
- Chambery
- Colmar
- Grenoble
- Hyeres
- Limoges
- Lyon
- Montpellier
- Nantes
- Nice
- Nimes
- Paris
- Perpignan
- Poitiers
- Rouen
- Saint Etienne
- Saint-Germain-En-Laye
- Strasbourg
- Tarbes
- Thionville
- Toulouse
- Tours
- Vandoeuvre-Lès-Nancy

Germany

- Aschaffenburg
- Bad Hersfeld
- Berlin
- Bonn
- Dortmund
- Duesseldorf
- Erlangen
- Hannover-Münden
- Muenchen
- Nuernberg
- Stuttgart
- Tuebingen
- Villingen-Schwenningen
- Wiesbaden
- Wiesloch
- Wuppertal

Greece

- Alexandroupolis
- Ioannina
- Larissa
- Piraeus
- Thessaloniki

Hungary

- Budapest
- Debrecen
- Miskolc
- Pecs

Italy

- Bergamo
- Cagliari
- Como
- Cremona
- Cuneo
- Genova
- Lecco
- Livorno
- Lodi
- Messina
- Modena
- Pavia
- Prato
- Reggio Calabria
- Roma
- Venezia
- Venezia Mestre

Mexico

- Cuernavaca
- Mexico City

Netherlands

- Amersfoort
- Heerlen

Norway

- Bergen
- Lillehammer
- Trondheim

Panama

- Panama City

Poland

- Gdansk
- Gdynia
- Kielce
- Krakow
- Lodz
- Poznan
- Rzeszow
- Szczecin
- Warszawa
- Wolomin
- Wroclaw

Portugal

- Porto
- Setubal

Russian Federation

- Moscow
- St. Petersburg

South Africa

- Cape Town
- Durban
- Johannesburg
- Soweto

Spain

- Alcorcon
- Alicante
- Almería
- Badalona
- Barcelona
- Bilbao
- Cordoba
- La Coruna
- Lerida
- Madrid
- Malaga
- Oviedo
- Palma de Mallorca
- Salamanca
- Santander
- Santiago de Compostela
- Sevilla

Sweden

- Huddinge
- Karlstad
- Stockholm
- Umea

Switzerland

- Aarau
- Lausanne

Taiwan

- Kaohsiung
- Taichung
- Taipei

Thailand

- Bangkok
- Chiang Mai
- Chonburi
- Phitsanulok

United Kingdom

- Belfast
- Cambridge
- Carshalton
- Dundee
- Exeter
- Glasgow
- Hertford
- Leicester
- London
- Salford
- Swansea

United States

- Birmingham, AL
- Mobile, AL
- Montgomery, AL
- Hot Springs, AR
- Covina, CA
- Encino, CA
- Irvine, CA
- Los Alamitos, CA
- Los Angeles, CA
- Mather, CA

- Monterey Park, CA
- Riverside, CA
- Sacramento, CA
- San Diego , CA
- San Francisco, CA
- San Jose, CA
- Stanford, CA
- Colorado Springs, CO
- Denver, CO
- Lakewood, CO
- Stamford, CT
- Ocala, FL
- Pembroke Pines, FL
- Tampa, FL
- Atlanta, GA
- Augusta, GA
- Honolulu, HI
- Chicago, IL
- Maywood, IL
- South Holland, IL
- Louisville, KY
- Baton Rouge, LA
- Shreveport, LA
- Boston, MA
- Springfield, MA
- Detroit, MI
- Kalamazoo, MI
- Brooklyn Center, MN
- Columbus, MS
- Tupelo, MS
- St. Louis, MO
- Las Vegas, NV
- Hackensack, NJ
- Paterson, NJ
- Albuquerque, NM
- Bronx, NY
- Brooklyn, NY
- Flushing, NY
- Great Neck, NY
- Mineola, NY
- New York, NY
- Orchard Park, NY
- Chapel Hill, NC
- Mount Airy, NC
- Raleigh, NC
- Cincinnati, OH
- Cleveland, OH
- Toledo, OH
- Oregon City, OR
- Portland, OR
- Allentown, PA
- Erie, PA
- Lewistown, PA
- Philadelphia, PA
- Pittsburgh, PA
- Ponce, PR
- San Juan, PR
- Columbia, SC
- Orangeburg, SC
- Chattanooga, TN
- Nashville, TN
- Austin, TX
- Dallas, TX
- Houston, TX
- San Antonio, TX
- Burlington, VT
- Charlottesville, VA
- Fairfax , VA
- Norfolk , VA

- Salem, VA
- Morgantown, WV
- Marshfield, WI

To contact Roche for more information on this trial please complete the email form below. Treatment decisions and/or suitability for a specific trial are decisions only your healthcare provider can make. Therefore, extensive medical information need not be include in your query. To guarantee timely processing of your query, please be concise.If you are patient interested in any of the studies, please have your healthcare provider contact us via this website, and they will be provided with the relevant clinical trial information.

Country* Please Select

Subject* Please Select

Your message

Last Name*

First Name*

Address

Telephone

E-mail*

your email address is needed for us to reply

Are you a:* Please Select

Send Clear Form