A randomized, double-blind, parallel group, placebo-controlled, multi-center study to assess the safety and tolerability of monthly subcutaneous administrations of a low and high dose cohort of Osocimab to ESRD patients on regular hemodialysis.

Published: 23-06-2020
Last updated: 09-04-2024

In this study researchers want to learn about the safety of drug Osocimab at low and high doses in adult participants with kidney disease undergoing regular dialysis. Patients with kidney disease undergoing regular dialysis are at high risk for...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON55066

Source
ToetsingOnline

Brief title
CONVERT

Condition

- Nephropathies
- Embolism and thrombosis

Synonym

thromboembolic events, thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: ESRD, factor XIa antibody, hemodialysis

Outcome measures

Primary outcome

Primary Outcome Measures:

• Composite of major and clinically-relevant non-major bleeding events as assessed by blinded Central Independent Adjudication Committee (CIAC) [Time Frame: From the first dose at month 1 and up to 6 months]

• Composite of moderate and severe adverse (AEs) and serious adverse events (SAEs) [Time Frame: From the first dose at month 1 and up to 6 months]

Secondary outcome

Secondary Outcome Measures:

• Activated partial thromboplastin time (aPTT) at trough levels [Time Frame: At baseline and after 6 months]. aPTT will be measured.

• Factor XIa (FXIa) activity at trough levels [Time Frame: At baseline and after 6 months]. Factor XI activity will be assessed.

Study description

Background summary

Study to investigate the safety of a drug called Osocimab at low and high doses in adult patients with kidney failure requiring regular hemodialysis.

Study objective

In this study researchers want to learn about the safety of drug Osocimab at low and high doses in adult participants with kidney disease undergoing regular dialysis. Patients with kidney disease undergoing regular dialysis are at high risk for heart and blood vessels diseases. Osocimab is a human monoclonal antibody under development for the prevention of events caused by blood clots like heart attack, stroke and death due to heart and blood vessels diseases without increasing the risk of bleeding. It works by binding to and blocking the activated form of clotting factor XI which increases the formation and stability of clots.
Researchers also want to find out how drug Osocimab works in human body and how the body absorbs, distributes and excretes the drug.

Study design

A randomized, double-blind, parallel group, placebo-controlled, multi-center study.

Intervention

This study compares 2 different doses of Osocimab with placebo:

Experimental: BAY1213790 low dose:
Participants will receive Osocimab (BAY1213790) 105 mg single loading dose as subcutaneous abdominal injection, followed by monthly maintenance doses of 52.5 mg starting at visit 8 until the end of the extension treatment period.

Placebo Comparator:
Placebo low dose. Placebo will be administered subcutaneously in the same manner as Osocimab.

Experimental: BAY1213790 high dose:
Participants will receive Osocimab (BAY1213790) 210 mg single loading dose as subcutaneous abdominal injection, followed by monthly maintenance doses of 105 mg starting at visit 8 until the end of the extension treatment period.

Experimental: Placebo high dose
Placebo will be administered subcutaneously in the same manner as Osocimab.

Study burden and risks

Patient's burden consists of the extra time investment during study participation. The patient will not be asked to bring extra visits to the hospital: all study visits are combined with the standard dialysis visits. However, the patient will spend a maximum of 30 minutes of extra time during the combined study visits if this visit concerns an IMP administration (within a period of min. 11 to max. 23 months). The patient will undergo physical examination 3x till 6x (resp. in 11 and 23 months study duration). There will be 17x till 33x heartbeat and blood pressure measurement (at every visit, dependent on visit duration) and 7x till 11x ECG measurement (dependent on study duration). Once a month (but more frequently at the beginning of the study), a blood sample will be taken via the hemodialysis line or catheter. The patient could experience a certain extent of burden during these actions and measurements.

The treatment consists of max. 18x a subcutaneous injection. A possible side effect of this can be hypersensitivity for the injection or allergic reactions to Osocimab. Because of this investigational product's nature, bleeding can be a possible side effect after Osocimab administration. In addition, the following side effects can be expected: low platelet count, development of antibodies that hinder Osocimab's effect.

When the burden and risks are adversely experienced by the patient, he or she is allowed to stop the study participation without any explicit reason and without any consequences for the medical care.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Participants must be at least 18 years of age
• Patients with end-stage renal disease on hemodialysis (including hemodiafiltration) for >=3 months, receiving dialysis at least 9 hours a week and stable in the view of the investigator
• Body weight of at least 50 kg
• Male and/or female. Contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies.

Exclusion criteria

• Recent (<6 months before screening) clinically significant bleeding
• Hemoglobin (Hb) < 9.0 g/dL at screening
• Platelet count < 100 x 10^9/L
• aPTT or PT > ULN (upper limit of normal)
• Hepatic disease associated with ALT > 3x ULN, or total bilirubin >2x ULN with direct bilirubin > 20% of the total
• Sustained uncontrolled hypertension (diastolic blood pressure >=100 mmHg and/or systolic blood pressure >= 180 mmHg)
• Known intracranial neoplasm, arteriovenous malformation or aneurysm
• Known bleeding disorders e.g. von-Willebrand disease or Hemophilia A, B or C
• Recent (<3 months before screening) thromboembolic event, e.g. acute coronary syndrome, stroke or VTE (except dialysis access thrombosis)
• Recent (<3 months before screening) major surgery or scheduled major surgery during study participation
• Scheduled living donor renal transplant during study participation
• Persistent heart failure as classified by the New York Heart Association

(NYHA) classification of 3 or higher
• Receiving antiplatelet therapy except daily ASA <= 150 mg/day
• Receiving anticoagulation in therapeutic doses, other than standard anticoagulation during the hemodialysis procedure

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2021
Enrollment:	23
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NVT
Generic name:	Osocimab

Ethics review

Approved WMO

Date:	23-06-2020
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-08-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-11-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	05-02-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-02-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-05-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-06-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-11-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-003957-27-NL
CCMO	NL73935.100.20

Study results

Results posted: 03-03-2023

First publication
01-01-1900

URL result
Type
ext
Naam
clinicaltrials.bayer.com
URL
Type
ext
Naam
clinicaltrials.gov
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