Multiple dose escalation study in a multicenter, randomized, single-blind, parallel-group, placebo-controlled design to investigate safety, tolerability, pharmacokinetics, and pharmacodynamics of BAY 1213790 administered subcutaneously in healthy male subjects.

Published: 06-09-2018
Last updated: 10-01-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46278

Source
ToetsingOnline

Brief title
Multiple dose escalation study of BAY 1213790.

Condition

- Other condition

Synonym
Venous thromboembolism

Health condition

Veneuze trombo-embolie.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: BAY 1213790, Venous thromboembolism

Outcome measures

Primary outcome

To investigate the safety and tolerability of BAY 1213790 administered

subcutaneously as a single loading dose followed by multiple maintenance doses

in healthy male subjects by means of frequency of TEAEs.

Secondary outcome

To investigate the PK of BAY 1213790 in plasma after multiple subcutaneous

doses

Study description

Background summary

BAY 1213790 is a new compound developed by the company Bayer AG that is

undergoing clinical development because of its characteristics for preventing thrombosis. Venous thromboembolism is a disease that includes both deep vein thrombosis and pulmonary embolism. It is a common, potentially fatal disorder that affects hospitalized and non-hospitalized patients and may lead to long-term complications. Thromboembolic disorders are a major cause of disease and death in the entire world, causing or contributing to acute coronary syndromes, embolic and thrombotic stroke, and peripheral arterial occlusion.

BAY 1213790 is a fully human monoclonal antibody that binds specifically to activated factor XI, one of the enzymes (= proteins that speeds up and guides processes in the body) responsible for the coagulation, resulting in modulation of the coagulation process.

Study objective

The purpose of this study is to investigate how safe the new compound BAY 1213790 is and how well it is tolerated when it is administered as an injection under the skin to healthy male volunteers. BAY 1213790 has been administered to humans before.

This study will be performed in 32 healthy male volunteers. The study will be performed at 3 clinical sites in The Netherlands and Germany.

The study will consist of up to 2 groups of 16 volunteers each. You can participate in one of these groups.

It will also be investigated how quickly and to what extent BAY 1213790 is absorbed and eliminated from the body (this is called pharmacokinetics). In addition, the effect of BAY 1213790 on indicators for blood clothing will be investigated (this is called pharmacodynamics).

The effects of BAY 1213790 will be compared to the effects of a placebo. A placebo is a medicine without any active ingredient. It is a *fake* medicine.

Study design

BAY 1213790 or placebo will be given as an s.c. injection.

During the first 4 hours after administration of the study compound the volunteer will have to lie down, and they are not allowed to eat. 'They may only drink water.

Whether the volunteer will receive BAY 1213790 or placebo will be determined by chance. They will have a 7 in 8 chance of receiving BAY 1213790 and a 1 in 8 chance of receiving placebo. Per group, 14 volunteers will receive BAY 1213790 and 2 volunteers will receive placebo. They will not be told if BAY 1213790 or

placebo will be administered, but the responsible doctor knows; we call this a single-blinded study.

Group 1 Day 1 ; BAY 1213790 100 mg or placebo once
Group 1 Day 29, 57, 85; BAY 1213790 35 mg or placebo once per dosing day
Group 2 Day 1; BAY 1213790 200 mg or placebo once
Group 2 Day 29, 57, 85; BAY 1213790 70 mg or placebo once per dosing day

Intervention

Group 1 Day 1 ; BAY 1213790 100 mg or placebo once
Group 1 Day 29, 57, 85; BAY 1213790 35 mg or placebo once per dosing day
Group 2 Day 1; BAY 1213790 200 mg or placebo once
Group 2 Day 29, 57, 85; BAY 1213790 70 mg or placebo once per dosing day

Study burden and risks

Pain, minor bleeding, bruising, possibly an infection.

Contacts

Public
Bayer AG

N/A N/A
Leverkusen D-51368
DE
Scientific
Bayer AG

N/A N/A
Leverkusen D-51368
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

white healthy male
18 - 55 years
weight less then 115 kilograms
BMI 18 - 29.9 kilograms/meter2

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study. Donation of more than 100 mL of whole blood or plasma within 4 weeks or 500 mL whole blood within 3 months before study drug administration.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-04-2019
Enrollment:	12

Type:	Actual

Ethics review

Approved WMO Date:	06-09-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-09-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-04-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-08-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2018-000838-34-NL
CCMO	NL67024.056.18

Study results

Date completed: 23-03-2020

Results posted: 26-01-2021

First publication
06-10-2020