EDOXABAN SWITCHING STUDY FOR APIXABAN

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Primary :To evaluate the prothrombin time (PT) in healthy volunteers treated with edoxaban alone or preceded by apixaban.Secondary : To assess the effect of edoxaban alone or preceded by apixaban on additional pharmacodynamic (PD) assays: activated...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON36871

Source
ToetsingOnline

Brief title
EDOXABAN SWITCHING STUDY FOR APIXABAN

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
blood clotting, Thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Daiichi Pharmaceutical
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Apixaban, Blood clotting, Edoxaban, Thrombosis

Outcome measures

Primary outcome

Pharmacodynamics, Pharmacokinetics, Safety

Secondary outcome

n/a

Study description

Background summary

Edoxaban is a new investigational compound that may eventually be used for the treatment of thrombosis, unwanted blood clotting, after major orthopedic surgery (artificial hip replacement and knee replacement) and in patients with atrial fibrillation, a heart arrhythmia. Edoxaban is an oral Factor 10 (FXa) inhibitor that works by blocking a part of the series of steps leading to the clotting of your blood (in this case activated FXa), Edoxaban is not registered as a drug in Europe (but is marketed in Japan since April 2011), and has been given to humans before.
During this study you will also receive Apixaban (marketed as Eliquis), a registered drug with a similar mechanism of action as the study drug.

Study objective

Primary :
To evaluate the prothrombin time (PT) in healthy volunteers treated with edoxaban alone or preceded by apixaban.

Secondary :
To assess the effect of edoxaban alone or preceded by apixaban on additional pharmacodynamic (PD) assays: activated partial thromboplastin time (aPTT), anti-factor Xa (FXa) activity, thrombin generation assay (TGA) parameters (endogenous thrombin potential [ETP].
To evaluate the single- and multiple-dose pharmacokinetics of edoxaban and metabolites.
To evaluate the single-dose pharmacokinetics of apixaban.

To evaluate the safety and tolerability of all treatments.

Study design

Open-label, 2-treatment, 2-way crossover study. Subjects will be randomized to a treatment sequence in Period 1. Each subject will receive the 2 treatments listed below in a random order:
* Treatment A: single oral doses of 60 mg edoxaban (administered as 2 x 30 mg) on Days 1 to 4
* Treatment B: 5 mg apixaban twice daily (bid) (administered as 2 x 2.5 mg) every 12 hours (q12h) on Days 1 to 3 followed by a single morning dose of edoxaban 60 mg (administered as 2 x 30 mg) on the morning of Day 4

Intervention

Treatment A: single oral doses of 60 mg edoxaban (administered as 2 x 30 mg) on Days 1 to 4 (all days inclusive)
Treatment B: 5 mg apixaban twice daily (bid) (administered as 2 x2.5 mg) every 12 hours (q12h) on Days 1 to 3 (all days inclusive) followed by a single morning dose of edoxaban 60 mg (administered as 2 x 30 mg) on the morning of Day 4

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

Contacts

Public
Daiichi Pharmaceutical

Chiltern Place Chalfont Park
Gerrards Cross, Buckinghamshire SL9 0BG
GB
Scientific
Daiichi Pharmaceutical

Chiltern Place Chalfont Park
Gerrards Cross, Buckinghamshire SL9 0BG
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy male and female (negative pregnancy test)
Age: 18-45 years (inclusive)
BMI: 18.0 - 30.0 (inclusive)

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/Aids. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters blood (males) or 1,0 liters blood (female) in the 10 months preceding the start of the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2012
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Apixaban
Generic name:	Eliquis
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-09-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-09-2012
Application type:	First submission
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	EUCTR2012-003375-18-NL
CCMO	NL41870.056.12