A Phase 3 Randomized, Double-blind, Parallel-group, Multi-center Study of the Safety and Efficacy of Apixaban for Prophylaxis of Venous Thromboembolism in Acutely Ill Medical Subjects During and Following Hospitalization

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To demonstrate that oral administration of apixaban 2.5 mg BID for 30 days reduces the rate of total venous thromboembolism (VTE) and VTE-related death compared to standard, subcutaneous administration of enoxaparin 40 mg QD for a recommended...

Ethical review	Approved WMO
Status	Pending
Health condition type	Embolism and thrombosis
Study type	Interventional

Summary

ID

NL-OMON33854

Source
ToetsingOnline

Brief title
ADOPT-CV185036

Condition

- Embolism and thrombosis

Synonym
thrombosis; bloedstolsel

Research involving
Human

Sponsors and support

Primary sponsor: Bristol-Myers Squibb
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: hospitalisation, profylaxis, venous thromboembolism

Outcome measures

Primary outcome

Composite of total VTE and VTE-related death during 30 days of double-blind treatment, where total VTE is defined as the combination of symptomatic deep vein thrombosis, fatal or nonfatal symptomatic pulmonary embolism and asymptomatic proximal deep vein thrombosis detected by compression ultrasound.

Secondary outcome

*Composite of total VTE, as defined above and VTE-related death occurring up to the time of discontinuation of parenteral therapy.

*Composite of total VTE, as defined above and all-cause death at Day 30.

*Adjudicated major bleeding events during 30 days of double-blind treatment.

*Composite of adjudicated major and clinically relevant non-major bleeding events during 30 days of double-blind treatment.

Study description

Background summary

A majority of hospitalized patients have risk factors for DVT and pulmonary embolism. Hospitalisation for medical illness is associated with an 8-fold increased relative risk for VTE.
In the absence of profylaxis the prevalence of VTE is estimated to be 10-20% in medical patients.
Therefore VTE profylaxis is a valuable treatment.
However the treatment is often not optimally effective due to failure to administer a dose, not optimal dosage or failure to continue prophylaxis throughout the period of elevated risk. Prophylaxis would benefit from from the availability of an agent that is safe and effective after oral administration.

Study objective

To demonstrate that oral administration of apixaban 2.5 mg BID for 30 days reduces the rate of total venous thromboembolism (VTE) and VTE-related death compared to standard, subcutaneous administration of enoxaparin 40 mg QD for a recommended minimum period of 6 days, in subjects with acute medical illness.

Study design

Randomized, double-blind, double-dummy, 2-arm, multi-center trial

Intervention

One arm recieves oral apixaban 2.5 mg BID and once daily 40 mg subcutaneous placebo fluid.
The other arm receives once daily subcutaneous enoxaparin 40 mg during hospitalization and oral placebo tablets 2.5 mg BID.

Study burden and risks

The study will last for 90 days with a total of 6 visits taking 30 to 60 minutes. The patient will undergo the following procedures:
1 x complete physical examination
5 x abbreviated physical examination
6 x vital signs
2 x bilateral compression ultrasound
2 x ECG
4 x mobility questionnaire
6 x venapunction (12 ml each time)
For WOCBP a pregnancy test (urine) is required (4 times)

The possible side effects for apixaban are:
Increased risk for bleeding, nausea, obstipation, fever, vomitting, oedema, arthralgia, sleeplessness, dizziness, erythema, itching, headache, tiredness,

stomach pain.

Contacts

Public
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Scientific
Bristol-Myers Squibb

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Hospitalized due to
- congestive heart failure
- acute respiratory failure
- infection (without septic shock)
- acute rheumatic disorder
- inflammatory bowel disease
2) Except for subjects with congestive heart failure or respiratory failure subjects must have one additional risk factor for VTE.
3) Expected hospitalisation 3 days or longer after randomisation

4) Severely or moderately restricted mobility

Exclusion criteria

1) Subjects who received more than 2 days of prophylaxis for VTE
2) Subjects with surgery in the past 30 days
3) Subjects with a condition that requires chronic anticoagulation
4) Subjects with active bleeding or at high risk of bleeding

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	155
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	apixaban
Generic name:	-
Product type:	Medicine
Brand name:	Lovenox

Generic name:	enoxaparin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-05-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-08-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-09-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-11-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-02-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-04-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-05-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-06-2008
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-11-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-02-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-02-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2006-003674-96-NL
ClinicalTrials.gov	NCT00457002
CCMO	NL17540.091.07