An open label, non-comparative, pharmacokinetic and pharmacodynamic study to evaluate the effect of Dabigatran Etexilate on coagulation parameters including a calibrated thrombin time test in patients with moderate renal impairment (creatinine clearance 30-50 ml/min) undergoing primary unilateral elective total knee or hip replacement surgery

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To asses the comparability of the estimated dabigatran concentration in plasma via calibrated Hemoclot and the measured dabigatran concentrations assessed in a central lab in patients with moderate renal impairment undergoing primary unilateral...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON34322

Source
ToetsingOnline

Brief title
BI trial no.: 1160.86

Condition

- Bone and joint therapeutic procedures
- Embolism and thrombosis

Synonym
prevention of venous thromboembolism

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Boehringer Ingelheim bv

Intervention

Keyword: coagulation parameters, dabigatran etexilate, knee or hip replacement surgery, renal impairment

Outcome measures

Primary outcome

Pharmacodynamic parameters:

- clotting time and calculated dabigatran plasma concentration

- aPTT

- ECT

Pharmacokinetic parameters:

- total dabigatran plasma concentrations in serial samples

- Cmax, AUC on day 6 (+/-1) and Cmin

Secondary outcome

Safety:

- adverse events

Study description

Background summary

There is limited clinical expierience with dabigatran etexilate administration to patients with moderate renal impairment. Some patients, e.g. elderly subjects with moderate to severe renal impairment, might be at increased risk of bleeds due to prolonged elimination of dabigatran. A follow-up measure was agreed with the EMEA to evaluate a calibrated commercial coagulation assay for the measurement of blood coagulation time in patients with moderate renal impairment.

Study objective

To asses the comparability of the estimated dabigatran concentration in plasma via calibrated Hemoclot and the measured dabigatran concentrations assessed in a central lab in patients with moderate renal impairment undergoing primary unilateral elective total knee or hip replacement surgery.

Study design

Multi-centre, open label, non-comparative uncontrolled study. All patients will be receiving dabigatran etexilate (Pradaxa) 150 mg taken once daily as 2 capsules of 75 mg; duration of treatment - 10 days. At day of surgery the treatment will be initiated 1-4 hours post surgery with half a dose (75 mg).

Intervention

All patients will receive 150 mg dabigatran etexilate (Pradaxa) taken once daily as 2 capsules of 75 mg, at the day of surgery the treatment will be initiated 1-4 hours post surgery with half a dose.

Study burden and risks

The standard profylaxis will be replaced by Pradaxa. Next to the planned surgery a physical examination will be performed and during the study 12 -13 venapunctures will be taken to obtain blood samples. Woman of child-bearing potential will undergo a urine prengnancy test.

Contacts

Public

Boehringer Ingelheim

Comeniusstraat 6
1817 MS Alkmaar
NL
Scientific
Boehringer Ingelheim

Comeniusstraat 6
1817 MS Alkmaar
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) patients scheduled for primary unilateral elective total knee or hip replacement, male or female being 18 years or older
2) moderate renal impairment (creatine clearance 30 - 50 ml/min)
3) written informed consent
4) caucasian patients

Exclusion criteria

1) Patients weighing less than 40 kg
2) patients requiring chronic treatment with anticoagulants
3) patients who in the investigators judgement are perceived as having an excessive risk of bleeding
4) recent unstable cardiovasculair disease
5) ongoing treatment for VTE;See page 19 - 21 of the study protocol for all exclusion criteria

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2010
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Pradaxa
Generic name:	dabigatran etexilate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	04-06-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	18-01-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2010-018723-26-NL
CCMO	NL32550.018.10