Single dose open-label PK/PD, safety and tolerability of dabigatran etexilate mesilate given at the end of standard anticoagulant therapy in successive groups of children aged 2 years to less than 12 years and 1 year to less than 2 years.

Published: 06-07-2012
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To provide single dose PK/PD dataTo investigate tolerability and safety of dabigatran etexilate solution in children1 to

Ethical review	Not approved
Status	Will not start
Health condition type	Embolism and thrombosis
Study type	Interventional

Summary

ID

NL-OMON37049

Source
ToetsingOnline

Brief title
1160.89

Condition

- Embolism and thrombosis

Synonym
bloodclot, deep venous thromboembolism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: children, dabigatran etexilate mesilate, direct thrombin inhibitor, venous thromboembolism (VTE)

Outcome measures

Primary outcome

- incidence of all bleeding events (major and minor);

- incidence of all adverse events.

Secondary outcome

- changes in laboratory and clinical parameters such as liver enzymes, ECG and

physical examination;

- occurrences of clinical outcomes including recurrent thrombosis, post

thrombotic syndrome (PTS), pulmonary emboli (PE), and total and venous

thrombolic event (VTE) related mortality objectively assessed for example by

ultrasound, venography or CT scan;

- global assessment of tolerability to studymedication.

Study description

Background summary

Single dose open-label PK/PD, safety and tolerability of dabigatran etexilate mesilate given at the end of standard anticoagulant therapy in successive groups of children aged 2 years to less than 12 years and 1 year to less than 2

years.

Study objective

To provide single dose PK/PD data
To investigate tolerability and safety of dabigatran etexilate solution in children
1 to <12 years of age

Study design

This is an open-label, multi-centre, non-randomised, uncontrolled, single dose, single
arm study.

Intervention

After completion of standard anticoagulation therapy the studymedication will be prescribed: dabigatran etexilate. The patient will visit the study site 3 times. During every visit a bloodsample is withdrawn and during visit 2 a total of 6 bloodsamples are withdrawn. During visit 1 and 3 a pregnancy test is performed (if applicable). During the first visit an ECG is performed. To avoid pregnancy, girls who have reached menarche need to use a medically accepted contraceptive method which is prescribed in the protocol.

Study burden and risks

After completion of standard anticoagulation therapy the studymedication will be prescribed: dabigatran etexilate. The patient will visit the study site 3 times. During every visit a bloodsample is withdrawn and during visit 2 a total of 6 bloodsamples are withdrawn. During visit 1 and 3 a pregnancy test is performed (if applicable). During the first visit an ECG is performed. To avoid pregnancy, girls who have reached menarche need to use a medically accepted contraceptive method which is prescribed in the protocol.

Contacts

Public
Boehringer Ingelheim

Comeniusstraat 6
ALKMAAR 1817 MS
NL
Scientific

Boehringer Ingelheim

Comeniusstraat 6
ALKMAAR 1817 MS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Stable pediatric patients objectively diagnosed with a venous thrombotic event

Exclusion criteria

- weight less than 9 kg;
- previous history of cerebral venous thromboembolism;
- conditions associated with a increased risk of bleeding;
- severe renal dysfunction;
- active infective endocarditis;
- hepatic disease.

Study design

Design

Study phase:	2
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	3
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Date:	06-07-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Not approved

Date:	25-07-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2009-013618-29-NL
Other	na
CCMO	NL41119.000.12