RE-SPECT CVT: a randomised, open-label, exploratory trial with blinded endpoint adjudication (PROBE), comparing efficacy and safety of oral dabigatran etexilate versus oral warfarin in patients with cerebral venous and dural sinus thrombosis over a 24-week period

Published: 14-09-2016
Last updated: 15-04-2024

See protocol sectie 2.1 & 2.2

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON45785

Source
ToetsingOnline

Brief title
RE-SPECT CVT

Condition

- Neurological disorders NEC

Synonym
cerebral venous and durale sinustrombosis

Research involving

Human

Sponsors and support

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

Intervention

Keyword: dabigatran etexilate, efficacy, safety, sinustrombosis

Outcome measures

Primary outcome

See protocol sectie 5.1.1.

Secondary outcome

See protocol sectie 5.1.2 & 5.1.3

Study description

Background summary

See protocol sectie 1.1

Study objective

See protocol sectie 2.1 & 2.2

Study design

See protocol sectie 3.1 & 3.2

Intervention

See protocol sectie 4.1 t/m 4.4

Study burden and risks

See protocol sectie 2.3

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Written informed consent in accordance with International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines and local legislation and/or regulations;- Confirmed diagnosis of Cerebral Venous or dural sinus thrombosis (CVT), with or without intracranial haemorrhage;- Completion of anticoagulation therapy for 5-15 days which has been administered until randomisation; anticoagulation must include full-dose low molecular weigth heparin or unfractionated heparin ;- Eligibility for treatment with an oral anticoagulant;Further inclusion criteria apply

Exclusion criteria

- CVT associated with central nervous system infection or due to head trauma;- Planned

surgical treatment for CVT;- Conditions associated with increased risk of bleeding;- History of symptomatic non-traumatic intracranial haemorrhage with risk of recurrence according to Investigator judgement;- Treatment with an antithrombotic regimen before CVT diagnosis and requiring continuation of that treatment for the original diagnosis without change in the regimen;- Severe renal impairment;- Active liver disease;- Preganancy, nursing or planning to become pregnant while in the trial

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2017
Enrollment:	15
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	14-09-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2018
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	EUCTR2015-004412-38-NL
CCMO	NL58256.018.16
Other	volgt