Extension trial to evaluate long term safety of patients randomised into 1160.113 RE-ALIGN study (RE-ALIGN-EX)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON39208

Source
ToetsingOnline

Brief title
RE-ALIGN-EX

Condition

- Cardiac valve disorders

Synonym
anticoagulant therapy in mechanical heartvalves

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim

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

Intervention

Keyword: dabigatran etexilate, direct thrombin inhibitor, mechanical heart valve, warfarin

Outcome measures

Primary outcome

There are no primary or secondary efficacy and safety variables. Clinical

efficacy and safety outcome variables, mortality and morbidity endpoints will

be evaluated in an exploratory manner and are described in Section 5.3.1.1 and

5.3.2.1. other endpoints.

Secondary outcome

See Sections 5.3.1.1 and 5.3.2.1 of the protocol for other endpoints.

Study description

Background summary

This study is an extension trial to the phase II study RE-ALIGN (study number 1160.113). It is designed to evaluate the long-term safety of dabigatran etexilate in patients who have received bileaflet mechanical heart valve replacement in the aortic and/or mitral position. Given the heterogeneity of the heart valve patient population and the complexity of optimal dosing, a long term observation of the safety of dabigatran etexilate in comparison to standard of care therapy with warfarin is warranted. With this trial all patients of the RE-ALIGN trial will be given the opportunity to continue on their treatment until the possible registration of dabigatran etexilate in this indication or if it is concluded that registration will not be pursued.

Study objective

The goal of this trial is to collect long-term observational data on the tolerability, safety and efficacy of dabigatran etexilate in a spectrum of patients receiving bileaflet mechanical heart valves. All patients that have completed study 1160.113 should be offered the opportunity to continue their

treatment for an extended period in this study.

Study design

It is a prospective, open label, active comparator trial with blinded endpoint adjudication.

Intervention

Patients will have successfully completed 1160.113 prior to inclusion into this study. Patients will remain on the treatment arm to which they were randomised in RE-ALIGN and receive either warfarin (maintained within the appropriate INR range) or dabigatran etexilate (same dose as at the end of 1160.113).

Study burden and risks

In order to monitor for these risk factors, data will be scrutinised on an ongoing basis by an independent external data safety monitoring board (DSMB) (no representative from the Sponsor will participate in their closed discussions). All data (for both dabigatran etexilate and warfarin patients), both adjudicated and non adjudicated will be reviewed by the DSMB in an ongoing fashion.
The study will be conducted under the guidance of an Operations Committee who will have an overall supervisory function. The use of electronic data capture should ensure quick turnaround times and up to date data for the independent DSMB to provide an unbiased review of data in a timely manner. Additionally, all bleeds and thromboembolic events will be reviewed by an Independent Adjudication Committee (IAC); data will be provided in discrete patient packets, removing data which could potentially provide information on the patients drug assignment (INR values for example) in order to ensure the IAC review is conducted in a blinded fashion.

Contacts

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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. Male and female patients aged over18 and below or equal 75 years at time of inclusion into 1160.113.
2. The patient must be able to give informed consent in accordance with ICH GCP guidelines and local legislation and/or regulations.
3. Continuing need for anticoagulation.

Exclusion criteria

1. Active infective endocarditis.
2. Uncontrolled hypertension (systolic blood pressure (SBP) >180mm Hg and/or diastolic blood pressure (DBP) >100mm Hg) as measured at baseline for this study (Visit 1).
3. Need for continued treatment with ticlopidine, ticagrelor, prasugrel, systemic ketoconazole, itraconazole, cyclosporine, tracrolimus, dronedarone, rifampicin, phenytoin, carbamazepine, St. John*s Wort or any cytotoxic/myelosuppressive therapy. See Section 4.2.2.
4. Recent malignancy or radiation therapy (since inclusion into 1160.113) unless the malignancy was a basal cell carcinoma that was completely removed.
5. Pre-menopausal (last menstruation <=1 year prior to screening) who:
• Are pregnant or nursing or
• Are not surgically sterile or
• Are of child bearing potential and not practising an acceptable method of birth control, or do not plan to continue practising an acceptable method of birth control throughout the trial (highly effective methods of birth control are defined as those, alone or in combination, that result in a low failure rate (i.e. less than 1% per year) when used consistently and correctly

[R09-1292].
6. Patients not willing or able to comply with the protocol requirements or considered unreliable by the Investigator concerning the requirements for follow-up during the study and/or compliance with study drug administration, have a life expectancy less than the expected duration of the trial due to concomitant disease or have any condition which, in the opinion of the Investigator, would not allow safe participation in the study (e.g. drug addiction, alcohol abuse).
7. Previous participation in this study.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2012
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	niet van toepassing
Generic name:	Warfarin
Product type:	Medicine
Brand name:	Pradaxa
Generic name:	dabigatran etexilate

Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	01-09-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-10-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-04-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-05-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-08-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-08-2012
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-11-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2011-002285-21-NL
CCMO	NL37360.060.11
Other	nog niet toegekend