Extension 1 to Protocol
A 2 year extension to a 36-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of aliskiren on the prevention of left ventricular remodeling in high risk post-acute myocardial infarction patients when added to optimized standard therapy

Published: 26-05-2008
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON32303

Source
ToetsingOnline

Brief title
ASPIRE extension

Condition

- Myocardial disorders

Synonym
heart attack, Myocardial infarct

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Farmaceutische industrie.

Intervention

Keyword: Acuut Myocardial Infarction (AMI), Aliskiren, Left ventricular remodeling

Outcome measures

Primary outcome

The primary objective of this Extension study is to provide additional

long-term safety data as a post marketing commitment to the EMEA. The

assessment of safety will be based primarily on the frequency of adverse

events, laboratory abnormalities, and serious adverse events.

Secondary outcome

The efficacy variables for this Extension study are:

* the change from baseline to the post-baseline measurement in LVESV as

assessed by echocardiography

* the change from baseline to the post-baseline measurement in LVEDV as

assessed by echocardiography

* the change from baseline to the post-baseline measurement in LVEF as

assessed by echocardiography

Study description

Background summary

Protocol CSPP1200A2340 is a 36 week long clinical trial designed to provide surrogate marker data [change in left ventricular end systolic volume (LVESV) as determined by echocardiography] for the efficacy and safety of aliskiren compared to placebo, when given in addition to optimized standard therapy in high-risk post-Acute Myocardial Infarction (AMI) patients. Protocol CSPP100A2340 is being extended by 2 years to obtain additional long-term safety data in this high-risk post-AMI patient population as part of a post-marketing commitment to the EMEA.

Study objective

The primary objective of this 2 year extension study (CSPP100A2340E1) is to provide additional long-term safety data in this patient population as a post marketing commitment to the EMEA.

A secondary objective is to provide additional follow-up data on the effect of aliskiren on left ventricular remodeling as measured by echocardiography - left ventricular end systolic volume (LVESV), left ventricular end diastolic volume (LVEDV), and left ventricular ejection fraction (LVEF).

Study design

Those patients that complete the original CSPP100A2340 *Core* study will be offered continued participation in an additional 2 year safety extension to the protocol. Those patients that agree to participate and sign a new Informed Consent Form, will be prescribed aliskiren, 150 mg OD for two weeks. Patients will then be up-titrated to 300 mg OD at the discretion of the principle investigator, based on the patients clinical condition, for the duration of the study (24 months/ 10 visits). In addition to their standard background therapies. These patients will be evaluated for long-term safety. Visit 1 must occur on or within 5 days after Visit 10 of the CSPP100A2340 *Core* study.

Intervention

At the completion of the *Core* study (Visit 10) all eligible patients that agree to continue in the open-label safety extension and sign the Informed Consent Form will be prescribed aliskiren, 150 mg OD for two weeks. Patients will then be up-titrated to 300 mg OD at the discretion of the principle investigator, based on the patients clinical condition, for the duration of the study.

Study burden and risks

Risks are possible side effects of study medicine or another medicine, and those of taking blood. The most common side effects reported in research studies to date with aliskiren were:
* Headache
* Dizziness
* Fatigue
* Abdominal pain
* Nausea
* Diarrhea
Problems or side effects that are not now known could also occur.

10 study visits will be payed to the medical center. The tests done at each study visit are standard medical tests. The most unpleasant is often having blood samples taken, which will be done every visit. The risks of taking blood may include pain and/or bruising.

The blood pressure cuff may also cause discomfort or bruising to the upper arm. Bloodpressure will be taken every visit. Physical examinations (3 times), electrocardiograms (ECGs; 3 times) and echocardiograms (ECHO; 2 times) are routine procedures in clinical practice and present practically no risk to the patient.

Contacts

Public
Novartis

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

See protocol for complete criteria (page 5)
Completed the CSPP100A2340 / ASPIRE study through visit 10 while on double-blind study drug.

Exclusion criteria

See protocol for complete criteria (page 5)
- NYHA class IV Congestive Heart Failure at Visit 1 (CSPP100A2340 "Core" Study Visit 10).
- Symptomatic hypotension, or reported systolic BP < 90 mmHg within the 24 hours prior to Visit 1.
- eGFR < 30 ml/min/1.73m2 using the MDRD formula at Visit 1.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	13-05-2008
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Rasilez
Generic name:	aliskiren
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	26-05-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-06-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-10-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-10-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-07-2012
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2008-001306-16-NL
CCMO	NL22413.042.08