A phase II multi-centre, double blind, placebo-controlled, dose focusing trial of CER-001 or placebo in subjects with Acute Coronary Syndrome (CER-001-CLIN-010, CARAT study)

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To assess the impact of 10 intravenous infusions of 3 mg/kg CER-001 versus placebo, given at weekly intervals, on atherosclerotic plaque volume, as measured by coronary IVUS, when administered to subjects presenting with an ACS event.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON42661

Source
ToetsingOnline

Brief title
CARAT

Condition

- Coronary artery disorders
- Lipid metabolism disorders

Synonym
acute coronary sydrome; ACS

Research involving
Human

Sponsors and support

Primary sponsor: Cerenis Therapeutics SA
Source(s) of monetary or material Support: Cerenis Therapeutics SA

Intervention

Keyword: ACS, CARAT, CER-001, IVUS

Outcome measures

Primary outcome

Change from baseline to follow-up in the percent atheroma volume in the target coronary artery assessed by 3D IVUS.

Secondary outcome

Change from baseline to follow-up in total atheroma volume (TAV) and change in TAV in the 10-mm sub segment of the coronary artery with the largest plaque volume at baseline. Adverse events.

Study description

Background summary

Despite the availability of several classes of very effective drugs, dyslipidemia and risk factor control are poorly served and there remains a large unmet medical need for new, effective and well tolerated therapies. There are a number of therapies given on a chronic basis to reduce long term risk, but subjects are at the highest risk immediately after an acute event. There is a high need for acute therapies which can be given at, or near, the time of an event, that will lead to rapid pacification of unstable plaque.
CER-001 negatively charged lipoprotein complex mimicking natural HDL, consisting of a combination of two naturally occurring phospholipids and recombinant human apolipoproteinA-I (apoA-I).
The primary aim of this study is to assess the impact of 10 intravenous infusions of 3 mg/kg CER-001 versus placebo on atherosclerotic plaque volume, as measured by coronary IVUS, when administered to subjects presenting with an Acute Coronary Syndrome (ACS) event.

Study objective

To assess the impact of 10 intravenous infusions of 3 mg/kg CER-001 versus placebo, given at weekly intervals, on atherosclerotic plaque volume, as measured by coronary IVUS, when administered to subjects presenting with an ACS event.

Study design

Randomized double-blind phase II parallel group study. Randomization (1:1) to:
• CER-001 3 mg/kg (10 weekly infusions in 30 minutes);
• Placebo infusions (normal saline).
At baseline subjects will be required to have at least one epicardial coronary artery suitable for IVUS imaging.
Randomization within 14 days of the ACS event.
IVUS imaging at baseline and 14 days after the end of treatment.
Study duration approx. 12 weeks (range 53-103 days).
600 screened, 292 randomized subjects.
If needed (because of condition of de subject or urgent need for interventions), the informed consent procedure at baseline may be reduced to the minimum: a 1+ page ICF and the most important questions. If needed the subject may give a verbal consent in the presence of a next of kin or independent witness, who will sign the consent form. After pacification of the situation/subject*s condition, the full written en verbal part of the consent procedure will take place, including signing the consent form when the subject has decided to proceed with the study.

Intervention

Treatment with CER-001 or placebo on top of regular treatment.

Study burden and risks

Risk: adverse events of study treatment.
Burden:
Visits: 12 visits (some will take place before discharge from hospital) in approx. 12 weeks.
Physical examination; twice.
Blood tests: 12 times (fasting) , 20-40 mL/occasion.
Urine tests: twice.
ECG: twice.
Cardiac catheterization (for study purposes only): once (after the end of study treatment).
IVUS (for study purposes): twice.

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

• Males and females, 18 years and above.
• Subjects who undergo coronary angiography within 7 days of presentation with ACS. Criteria for myocardial infarction and unstable angina see protocol page 6.
• Admission criteria for baseline coronary angiogram related to IVUS. See protocol page 7 for details.
• Randomization within 14 days of ACS presentation.
• Baseline IVUS completed and of acceptable quality.
• Females of childbearing potential: hormonal contraception or double barrier method during study.

Exclusion criteria

• Uncontrolled diabetes defined as HbA1c > 10% at screening.
• Triglycerides >500 mg/dL at screening.
• Coronary artery bypass graft surgery in previous 6 weeks or planned.
• Myocardial infarction in the target coronary artery for IVUS between the initial IVUS examination and randomization.
• Heart failure NYHA class III or IV.
• Ejection fraction <35%.
• Renal dysfunction CrCl <=30 ml/min.
• Participation in any investigational drug or interventional device study within 30 days.
• Participation in another CER-001 trial.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2015
Enrollment:	83
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	CER-001
Generic name:	CER-001

Ethics review

Approved WMO Date:	12-06-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-07-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-09-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-09-2015
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
Other	clinicaltrials.gov; registratienummer n.n.b.
EudraCT	EUCTR2015-001381-26-NL
CCMO	NL53502.100.15