Study of ARC1779 in patients with acute myocardial infarction undergoing percutaneous coronary intervention (PCI) (vITAL-1)

Submission date	Recruitment status	☐ Prospectively registered
10/01/2008	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/02/2008	Stopped	☐ Results
Last Edited	Condition category	☐ Individual participant data
08/08/2008	Circulatory System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Michael Gibson

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00507338

Secondary identifying numbers

ARC1779-003

Study information

Scientific Title

A phase 2 study of an aptameric von Willebrand Factor antagonist, ARC1779, in patients with acute myocardial infarction undergoing percutaneous coronary intervention

Acronym

vITAL-1

Study objectives

Adjunctive anti-thrombotic therapy for PCI of Acute Myocardial Infarction (AMI) may be improved by incorporation of a novel anti-platelet therapeutic principle, von Willebrand Factor antagonism. ARC1779 is a therapeutic oligonucleotide ("aptamer") which blocks the binding of the A1 domain of vWF to the platelet GP1b receptor, and thereby modulates platelet adhesion, activation, and aggregation under the high shear conditions of coronary arterial stenosis and plaque rupture. This study is intended to provide dose-ranging and clinical proof of concept for ARC1779 in a primary PCI population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical University of Vienna and the General Hospital of the City of Vienna. Date of approval: 27 November 2007

Study design

Randomized, double-blind (subject, caregiver, investigator, outcomes assessor), active control, parallel assignment, multi-center, safety/efficacy study.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Acute myocardial infarction

Interventions

Please note that as of 14/05/2008 this trial was terminated.

Procedure: Primary PCI

Study Drugs: Active control - Abciximab (ReoPro®) labeled regimen for primary PCI.

Investigational agent - ARC1779 Injection 0.1 mg/kg, 0.3 mg/kg, or 1.0 mg

Duration: Bolus + 12 hr infusion Frequency: 1 x treatment

Mode of Administration: Intravenous

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

aptameric von Willebrand Factor antagonist (ARC1779)

Primary outcome measure

Adequacy of reperfusion (Time frame: 48 hours post-PCI)

Secondary outcome measures

Bleeding (Time frame: PCI to hospital discharge)

Overall study start date

01/10/2007

Completion date

31/10/2008

Reason abandoned (if study stopped)

Trial terminated due to the mode of administration of drug being unfeasible for this proposed indication. Please keep reason for termination confidential.

Eligibility

Key inclusion criteria

- 1. Troponin-positive Non-ST-segment Elevation Myocardial Infarction (NSTEMI), with diagnostic symptoms and/or electrocardiogram (ECG) abnormalities present within the preceding 24 hours, and a planned "early invasive" management strategy
- 2. ST-Segment Elevation Myocardial Infarction (STEMI), with planned primary PCI

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

300

Key exclusion criteria

- 1. History of bleeding diathesis or evidence of active abnormal bleeding within the previous 30 days
- 2. Received treatment with fibrinolytic or GPIIb/IIIa antagonist drugs within the preceding 72 hours
- 3. Received anticoagulant therapy with a low molecular weight heparin within the preceding 8 hours
- 4. Severe hypertension (systolic blood pressure >200 mmHg or diastolic blood pressure >110 mmHg) not adequately controlled on antihypertensive therapy
- 5. Major surgery or trauma within the preceding 6 weeks
- 6. History of stroke within 30 days or any history of hemorrhagic stroke
- 7. End-Stage Renal Disease (ESRD) with dependency on renal dialysis

Date of first enrolment

01/10/2007

Date of final enrolment

31/10/2008

Locations

Countries of recruitment

Austria

Canada

Germany

Israel

Poland

Russian Federation

United States of America

Study participating centre 350 Longwood Avenue

Boston United States of America 02115

Sponsor information

Organisation

Archemix Corp (USA)

Sponsor details

300 3rd Street Cambridge United States of America 02142 +1 617 621 7700 jgilbert@archemix.com

Sponsor type

Industry

ROR

https://ror.org/00v8tzb98

Funder(s)

Funder type

Industry

Funder Name

Archemix Corp (USA)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration $% \left(1\right) =\left(1\right) \left(1\right) \left($