

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Intentional

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

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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