ISRCTN01837376 https://doi.org/10.1186/ISRCTN01837376

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00507338

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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

Key secondary outcome(s)
Bleeding (Time frame: PCI to hospital discharge)

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

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)

ROR
https://ror.org/00v8tzb98

Funder(s)

Funder type
Industry

Funder Name
Archemix Corp (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration