IOCYTE AMI-3: A Phase 3, Randomized, Double-Blind, Placebo- Controlled, Multicenter Study of Intravenous FDY-5301 in Patients with an Anterior ST-Elevation Myocardial Infarction

Published: 23-03-2022
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This study has been transitioned to CTIS with ID 2024-514372-40-00 check the CTIS register for the current data. Primary objective: To assess the effect of FDY-5301 on cardiovascular mortality and heart failure events in subjects with an anterior...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON54138

Source
ToetsingOnline

Brief title
IOCYTE AMI-3

Condition

- Myocardial disorders

Synonym
myocardial infarction, STEMI

Research involving
Human

Sponsors and support

Primary sponsor: Faraday Pharmaceuticals, Inc.
Source(s) of monetary or material Support: industry

Intervention

Keyword: Heart Diseases, Myocardial Infarction, STEMI

Outcome measures

Primary outcome

The proportion of subjects who experience either cardiovascular mortality (defined as deaths which are sudden and due to presumed arrhythmia, or deaths due to presumed or confirmed thromboembolic cerebral vascular accident, presumed or confirmed pulmonary embolism, cardiac rupture, heart failure, recurrent myocardial infarction [e.g., remote or stent thrombosis], and deaths due to procedural efforts to treat these defined cardiac events), or a heart failure event through Month 12.

Secondary outcome

Secondary Endpoints:

- The proportion of subjects who experience either all-cause mortality or a heart failure event through Month 12
- The total number of cardiovascular events defined as cardiovascular mortality and heart failure events through Month 12
- The proportion of subjects who experience a composite the following specified non-fatal cardiovascular events of thromboembolic cerebral vascular accident (CVA), ventricular aneurysm/hemorrhage, recurrent myocardial infarction (e.g.,

remote or stent thrombosis), or persistent arrhythmia requiring intervention (e.g., ventricular fibrillation, sustained ventricular tachycardia, or bradyarrhythmia requiring intervention) through Month 12

- Serum troponin T at Day 3

Exploratory Endpoints:

Individual adverse cardiovascular event outcomes will be evaluated as follows:

- Non-fatal thromboembolic CVA through Month 12

- Non-fatal ventricular aneurysm/hemorrhage through Month 12

- Non-fatal recurrent myocardial infarction (e.g., remote or stent thrombosis) through Month 12

- Persistent requiring intervention (e.g., ventricular fibrillation, sustained ventricular tachycardia, or bradyarrhythmia requiring intervention) arrhythmia through Month 12

- Heart failure managed with initiation or intensification of oral treatment through Month 12

- The proportion of subjects who experience all-cause mortality through Month 12

Study description

Background summary

The first line of therapy for acute ST-elevation myocardial infarction (STEMI) includes coronary artery reperfusion by mechanical means during primary percutaneous coronary intervention (pPCI). While clearly effective, it does not address the issue of reperfusion injury, a secondary damage that occurs

immediately due to the reoxygenation of the previously ischemic myocardial tissue and contributes to overall final infarct size (IS). Even though pPCI has dramatically improved the survival rate, the goal of developing FDY-5301 in acute myocardial infarction (AMI) is to further improve cardiovascular outcomes such as all-cause mortality, cerebral vascular accident (CVA), recurrent myocardial infarction (e.g., remote or stent thrombosis), and persistent arrhythmia after AMI.

Study objective

This study has been transitioned to CTIS with ID 2024-514372-40-00 check the CTIS register for the current data.

Primary objective:
To assess the effect of FDY-5301 on cardiovascular mortality and heart failure events in subjects with an anterior STEMI undergoing pPCI.

Secondary objective:
To assess the effect of FDY-5301 on other clinical outcomes such as all-cause mortality and cardiovascular outcomes in subjects with an anterior STEMI undergoing pPCI.

Study design

Randomized, Double-Blind, Placebo- Controlled Study.

Intervention

FDY-5301 (2 mg/kg) will be administered as a single IV bolus injection or Placebo (normal saline) will be administered as a single IV bolus injection. Placebo will be volume-matched and indistinguishable from FDY-5301.

Study burden and risks

FDY-5301 has been tested in approximately 140 study participants, including a study of 91 STEMI participants who received FDY-5301, and no known clinically significant side effects related to FDY-5301 were reported. These study participants received a single IV dose of FDY-5301 at doses that were either below, the same as, or above what is being given for this study.

The following theoretical side effects can occur:
- Over or under production of the thyroid hormone. Overproduction can cause symptoms such as jitteriness, feeling warm, or a fast pulse rate. Underproduction can cause symptoms such as feeling cold, tiredness, constipation, hair loss, or a slow heart rate.
- Too much iodide could possibly cause gastrointestinal (gut) irritation and

bleeding.

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

1. Age >= 18 years
2. Anterior STEMI, based on: Symptoms of myocardial ischemia (such as chest pain, shortness of breath, jaw pain, arm pain, diaphoresis, or any anginal equivalent) and

Electrocardiogram (ECG) criteria:
• men > 40 years: >= 2 mm of ST elevation in V2 and V3
• men <= 40 years: >= 2.5 mm of ST elevation in V2 and V3
• women >= 1.5 mm of ST elevation in V2 and V3

3. Planned primary PCI to occur <= 6 hours of onset of persistent symptoms that caused the patient to pursue medical care for myocardial infarction.
4. Institutional Review Board (IRB) / Independent Ethics Committee (IEC) approved consent obtained for study participation

Exclusion criteria

1. Life expectancy of less than 1 year due to non-cardiac pathology
2. Known thyroid disease or thyroid disorder, including subjects on thyroid hormone replacement therapy at the time of randomization
3. Known allergy to iodine or the excipient of the investigational product (sodium chloride)
4. Renal disease requiring dialysis
5. Women who are pregnant or breastfeeding. Women of reproductive potential must have a negative pregnancy test prior to randomization
6. Body weight >140 kg (or 309 lbs)
7. Use of thrombolytic therapy as treatment for the index STEMI event
8. Use of investigational drugs within 30 days or 5 half-lives whichever is longer, prior to randomization or the use of investigational devices within 30 days prior to randomization
9. Any clinically significant abnormality identified prior to randomization that in the judgment of the Investigator or Sponsor would preclude safe completion of the study, or confound the anticipated benefit of FDY-5301

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	25-08-2022
Enrollment:	260
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	FDY-5301
Generic name:	sodium iodide

Ethics review

Approved WMO Date:	23-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-06-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-09-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-01-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	03-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-12-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-01-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EU-CTR	CTIS2024-514372-40-00
EudraCT	EUCTR2021-001924-16-NL
ClinicalTrials.gov	NCT04837001
CCMO	NL79392.091.22