Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the safety and feasibility of collagen patch loaded with epicardial follistatin-like 1 (FSTL1) for treatment of myocardial ischemic injury

Protocol summary

Study aim
Evaluating the safety and feasibility of collagen patch with Follistatin-like 1 for heart failure following ST segment elevation myocardial injury

Design
Single-arm study , open label, 9 patients (3 in the feasibility and 6 in safety phase)

Settings and conduct
At Tehran Heart Centre patients undergo the intervention and are followed for 6 months.

Participants/Inclusion and exclusion criteria
Inclusion: 18<Age<80 first-time ST-elevation myocardial injury (MI) recommendation of isolated coronary artery bypass (CABG) within less than 3 months ejection fraction ≥ 20% and ≤ 40% due to ischemia no planning for pregnancy Exclusion: history of constrictive pericarditis history of surgery on pericardium pregnancy corticosteroid medications, or chemotherapy cancer glomerular filtration rate < 60 candidate for other types of cardiac surgery malignant ventricular arrhythmia or atrial flutter severe mitral valve stenosis or insufficiency severe aortic valve stenosis or insufficiency poor echo views severe hepatic failure estimated life expectancy of less than one year history of cardiac surgery contraindications for conducting cardiac magnetic resonance imaging International normalised ratio > 1.5 pulmonary disease dementia, Alzheimer, Parkinsonism, stroke with physical secuela.

Intervention groups
In the feasibility group, bioengineered collagen patch are transferred to infarct area during coronary artery bypass grafting . In the "safety" phase, patches are loaded with "follistatin like 1" and then transferred to the infarct area.

Main outcome variables
1.Feasibility (stiffness, suture ability, physio-mechanical properties) 2.Safety(death, rejection, allergic reaction, new myocardial infarction , new arrhythmia, pericardial effusion, tamponade, liver/kidney adverse effects) 3.Cardiac function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210827052304N1**
Registration date: **2022-09-12, 1401/06/21**
Registration timing: **retrospective**

Last update: **2022-09-12, 1401/06/21**
Update count: **0**

Registration date
2022-09-12, 1401/06/21

Registrant information

Name
Mana Jameie

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-26, 1397/07/04

Expected recruitment end date
2019-05-20, 1398/02/30

Actual recruitment start date
2018-09-26, 1397/07/04

Actual recruitment end date
2019-05-20, 1398/02/30
Trial completion date
2019-11-26, 1398/09/05

Scientific title
Evaluating the safety and feasibility of collagen patch loaded with epicardial follistatin-like 1 (FSTL1) for treatment of myocardial ischemic injury

Public title
Evaluation of the safety and feasibility of FSTL-1 cardiac patch
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 80 years old The first-time episode of myocardial infarction (MI) ST-elevation on the patient's electrocardiogram (ECG) Recommendation of isolated coronary artery bypass (CABG) by treating cardiologists or cardiac surgeons after conducting coronary angiography Less than 3 months delay between MI and upcoming operation Ejection fraction ≥ 20% and ≤ 40% Ischemia (rather than other cardiac problems) causing heart failure No planning for pregnancy during the study period for female participants
Exclusion criteria:
Previous history of constrictive pericarditis Past history of surgery on pericardium Pregnancy Being on immunosuppressive therapy Corticosteroid medications, or chemotherapy (or any plan for being on such treatments within the next 6 months after recruitment) Current or past history of cancer Current or previous history of autoimmune disorders Severe renal disorder (glomerular filtration rate < 60 ml/min/1.73 m2 Being a candidate for any types of cardiac surgery concomitant with coronary artery bypass surgery Having malignant ventricular arrhythmia or atrial flutter Severe mitral valve stenosis or insufficiency Severe aortic valve stenosis or insufficiency Patients with poor echo views Severe hepatic failure or cirrhosis Estimated life expectancy of less than one year Previous history for undergoing cardiac surgery Any contraindication for conducting cardiac magnetic resonance image Any tendency for perioperative bleeding (international normalized ratio > 1.5) Having pulmonary disease with forced expiratory volume < 50% or diffusing capacity of the lungs for carbon monoxide < 50% Having dementia, Alzheimer, Parkinsonism, and/or previous stroke with physical secuela.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **9**
Actual sample size reached: **9**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of National Institute for Medical Research Development (NIMAD)
Street address
National Institute of Medical Research Development of Iran (NIMAD), No. 21, at the beginning of Baath St., Fatemi West St., Tehran
City
تهران
Province
Tehran
Postal code
1419693111
Approval date
2016-12-26, 1395/10/06
Ethics committee reference number
IR.NIMAD.REC.1395.073

Health conditions studied

1

Description of health condition studied
ST-segment elevation MI
ICD-10 code
I21
ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

2

Description of health condition studied
Ischaemic Heart failure
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
Stiffness of the patch
Timepoint
Before and during the surgery
Method of measurement
Assessment of surgeons and bio-engineers of the patches outside the patients body and inside during surgery

2

Description
Suturablity of the patch
Timepoint
Before and during surgery
Method of measurement
Assessment of surgeons and bio-engineers of the patches outside the patients body and inside during surgery

3

Description
Death
Timepoint
During surgery and until 6 months post-operatively
Method of measurement
Physical examination

4

Description
New acute myocardial infarction
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking , physical examination, cardiac enzymes, echocardiograpghy, electrocardiogram

5

Description
Allergic reaction
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking , physical examination, laboratory tests

6

Description
Patch rejection
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking , physical examination, laboratory tests

7

Description
New arrhythmia
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking, electrocardiography , echocardiography

8

Description
New significant pericardial effusion
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking , physical examination , echocardiography

9

Description
New cardiac tamponade
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking , physical examination , echocardiography

10

Description
New acute pericarditis
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking , physical examination , echocardiography

11

Description
New drug-induced liver injury
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking, physical examination, liver function test

12

Description
New acute renal injury

Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking, physical examination, renal function test

13

Description
Drug induced myelosupression
Timepoint
After operation and until 6 months post-operatively (before discharge, 1 month, 3 months and 6 months after surgery)
Method of measurement
History taking, physical examination, CBC, if required : bone marrow aspiration

Secondary outcomes

1

Description
Left ventricular ejection fraction
Timepoint
Before and after surgery up until 6 months (before discharge, 1st, 3rd and 6th month after surgery)
Method of measurement
Echocardiography, cardiac magnetic resonance imaging

2

Description
Global longitudinal strain
Timepoint
Before and after surgery up until 6 months (before discharge, 1st, 3rd and 6th month after surgery)
Method of measurement
Echocardiography

3

Description
Myocardial extracellular volume
Timepoint
Before operation and 6 month post-operative
Method of measurement
cardiac magnetic resonance imaging

4

Description
Native T1 mapping
Timepoint
Before operation and 6 month post-operative
Method of measurement
cardiac magnetic resonance imaging

Intervention groups

1

Description
Intervention group: Acellular collagen patch (E = 10 kilopascal) fabricated through plastic compression and loaded with 10 micro grams of recombinant bacterial-synthetized human follistatin like 1 per patch which is grafter to the infarct area through coronary artery bypass surgery. Patches were purified using High performance liquid chromatography (HPLC) test and endotoxin test was performed on patches.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Hear Centre
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National institute for medical search development (NIMAD)
Full name of responsible person
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Web page address
http://nimad.ac.ir/
Grant name
NIMAD
Grant code / Reference number
۹۴۲۸۹۳
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National institute for medical search development (NIMAD)
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Mana Jameie
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available