Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of once versus twice intracoronary injection of allogenic Wharton's jelly derived mesenchymal stem cell in improving ejection fraction of patients with post myocardial infarction moderate to severe reduced ejection fraction

Protocol summary

Study aim
Comparing the effects of once versus twice intracoronary injection of allogenic Wharton's jelly derived mesenchymal stem cell in improving ejection fraction of patients with post myocardial infarction moderate to severe reduced ejection fraction

Design
Three arm parallel group randomized trial with blinded outcome assessment

Settings and conduct
Hospital setting equipped with cardiology units. Outcome assessment (the interpretation of echocardiographic findings) will be done by a physician blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion: Ages20- 60 Years Genders: Both First MI within 3 to 5 days Post AMI LVEF less than 40% as assessed by echocardiography Negative pregnancy test (in women with childbearing potential) Exclusion History of prior anterior myocardial infarction Patients with regional wall motion abnormalities in the non-infarct region prior CABG significant valve disease; defined as stenosis or regurgitation graded as greater than moderate (2+) Patients with another etiology of LV dysfunction (known/suspected non ischemic cardiomyopathy, previous anthracycline therapy, known ethanol abuse (greater than 6 oz. ethanol/day on a regular basis). Poor echocardiography window Active infection or history of recurrent infection or positive test for syphilis (RPR), hepatitis B and C (HBsAg, Anti-HCV), HIV and HTLV-1 Documental Terminal illness or malignancy Previous bone marrow transplant. Autoimmune disease (e.g.Lupus, Multiple Sclerosis)

Intervention groups
1) 20 patients will receive 1 injection of allogenic mesenchymal cells derived from Wharton's Jelly. 2) 20 patients will receive 2 injections of allogenic mesenchymal stem cells derived from Wharton's Jelly with 1 month interval. 3) control group will receive standard treatment of PCI.

Main outcome variables
effects of stem cell injection(once vs twice) on echocardiographic findings.

General information

Reason for update
Since preclinical studies have shown that Wharton's jelly derived mesenchymal stem cells are most effective when transplanted to heart, it was decided to change the source of the cells to this tissue.

Acronym

IRCT registration information
IRCT registration number: **IRCT20201116049408N1**
Registration date: **2020-11-20, 1399/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-26, 1399/09/06**
Update count: **1**

Registration date
2020-11-20, 1399/08/30

Registrant information

Name
Armin Attar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3628 3353

Email address
attar_armin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effects of once versus twice intracoronary injection of allogenic Wharton's jelly derived mesenchymal stem cell in improving ejection fraction of patients with post myocardial infarction moderate to severe reduced ejection fraction

Public title
Effect of once versus twice injection of stem cell for patients with myocardial infarction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Ages20- 60 Years Genders: Both First MI within 3 to 5 days Post AMI LVEF less than 40% as assessed by echocardiography Negative pregnancy test (in women with childbearing potential)

Exclusion criteria:
History of prior anterior myocardial infarction Patients with regional wall motion abnormalities in the non-infarct region prior CABG Patients with significant valve disease; defined as stenosis or regurgitation graded as greater than moderate (2+) Patients with another etiology of LV dysfunction (known/suspected non ischemic cardiomyopathy, previous anthracycline therapy, known ethanol abuse (greater than 6 oz. ethanol/day on a regular basis). Poor echocardiography window Active infection or history of recurrent infection or positive test for syphilis (RPR), hepatitis B and C (HBsAg, Anti-HCV), HIV and HTLV-1 Documental Terminal illness or malignancy Previous bone marrow transplant Autoimmune diseases

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was done based on permuted balanced block method. Patients after inclusion and giving informed consent, were allocated to blocks of 6 using table of random numbers. Allocation concealment was adequate (the person who executed the allocation sequence was different from the person who recruited participants and had no direct contact with patients)

Blinding (investigator's opinion)
Single blinded

Blinding description
The person doing the echocardiography and MRI exams is unaware of the groupings.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz university of Medical Sciences

Street address
Zand avenue

City
shiraz

Province
Fars

Postal code
34786-71946

Approval date
2020-06-20, 1399/03/31

Ethics committee reference number
IR.SUMS.REC.1399.406

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction

ICD-10 code
121.9

ICD-10 code description
Acute myocardial infarction, unspecified

Primary outcomes

1

Description
Ejection Fraction

Timepoint
within 6 months of intervention

Method of measurement
echocardiography

Secondary outcomes

1

Description
hematologic variables, cardiac imaging (MRI), electrocardiogram
Timepoint
2 weeks , 3 months , and 6 months after intervention
Method of measurement
lab kit for hematologic variables

Intervention groups

1

Description
Intervention group: once injection of adipose tissue stem cells
Category
Treatment - Other

2

Description
Intervention group: twice injection of adipose tissue stem cells
Category
Treatment - Other

3

Description
Control group: received standard care (for example PCI) for cardiac infarction with no further intervention.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital, Al-zahra hospital
Full name of responsible person
Armin Attar
Street address
Zand avenue, Shiraz, Iran
City
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Fars
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34786-71946
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+98 71 3612 8258
Email
attar_armin@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abbas Rezaeianzadeh
Street address
zand avenue
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Phone
+98 71 3235 7282
Email
rezaiana@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
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
Shiraz University of Medical Sciences
Full name of responsible person
Ahmad monabati
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Pathology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Kamran Hessami

Position

Research Assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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34786-71946

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Email

hessamikamran@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

all collected deidentified data

When the data will become available and for how long

available within 1 month after publication

To whom data/document is available

All researchers affiliated with academic settings.

Under which criteria data/document could be used

no restriction applied.

From where data/document is obtainable

Email contact with corresponding author: attar_armin@yahoo.com

What processes are involved for a request to access data/document

Email contact with corresponding author

Comments