Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study of the effect of Platelet Rich Fibrin (PRF) in closure of non-healing Sternum wound after open-heart Surgery

Protocol summary

Study aim
Study of the effect of Platelet Rich Fibrin (PRF) in closure of non-healing Sternum wound after open-heart Surgery

Design
Clinical trial has been designed with control group, treatment group, with parallel groups, blind, randomized

Settings and conduct
The patients will be referred to the Shahid Madani Hospital who have undergone bypass surgeries and will be divided into two groups, after satisfaction, who will receive randomized, double-blind, platelet-rich fibrin therapy.

Participants/Inclusion and exclusion criteria
Inclusion criteria:The patient has been diagnosed with an acute STEMI or NSTEMI; The patient is scheduled to undergo coronary artery bypass surgery; The patient does not possess any contraindication for cardiovascular magnetic resonance (CMR); The patient is capable of giving informed consent; The patient is geographically accessible and willing to return for all follow-up investigations and clinical visits associated with study. Exclusion criteria:The patient has previous myocardial infarction (MI) and/or has scar or non-viable myocardium identified; The patient is undergoing other cardiac surgery; The patient requires emergency surgery within 24-hrs of assessment; The patient has undergone previous cardiac surgery

Intervention groups
Patients experimental group: who will receive Platelet Rich Fibrin (PFR) suspension with standard medical therapy placebo experimental group: who will receive standard medical therapy

Main outcome variables
the effect of Platelet Rich Fibrin (PRF) in closure of sternum wound

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170221032714N4**
Registration date: **2018-03-29, 1397/01/09**
Registration timing: **prospective**

Last update: **2018-03-29, 1397/01/09**
Update count: **0**

Registration date
2018-03-29, 1397/01/09

Registrant information

Name
Peyman Keyhanvar

Name of organization / entity
Stem Cell and Regenerative Medicine Institute, Tabriz University of Medical Sciences, Tabriz, Iran

Country
Iran (Islamic Republic of)

Phone
+98 914 114 6863

Email address
keyhanvarp@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2019-04-06, 1398/01/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of Platelet Rich Fibrin (PRF) in closure

of non-healing Sternum wound after open-heart Surgery

Public title
Applicability of Platelet Rich Fibrin (PRF) in closure of non-healing Sternum wound

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient has been diagnosed with an acute STEMI or NSTEMI (confirmed by segment elevation (ST) changes on serial ECG, elevated troponin, coronary artery stenosis or occlusion identified by angiography, and a wall motion abnormality identified by angiography or echocardiography); The patient is scheduled to undergo coronary artery bypass surgery;The patient does not possess any contraindication for cardiovascular magnetic resonance (CMR); The patient is capable of giving informed consent; The patient is geographically accessible and willing to return for all follow-up investigations and clinical visits associated with study.

Exclusion criteria:
The Exclusion criteria of study: The patient is over the age of 65 years; The patient has previous myocardial infarction (MI) (other than the qualifying event) and/or has scar or non-viable myocardium identified by CMR in any other left ventricular (LV) territory; The patient is undergoing other cardiac surgery (i.e. concurrent cardiac valve, or aortic surgery); The patient requires emergency surgery (i.e. operative intervention (CABG or ventricular assist device) within 24-hrs of assessment); The patient has undergone previous cardiac surgery; The patient's post-surgical life expectancy is less than 45 days, in the investigator's opinion; The patient is of excessively poor baseline health, health-related quality of life, or physical functioning that would preclude a reasonable expected post-operative recovery; The patient has received radiotherapy to the chest wall, is receiving immunosuppressive therapy, or is in any way immunocompromised.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will take place in base on a restricted, block randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
Blind groups will include participating and research groups. In case of blindness, based on a doctor's request, a placebo and active treatment will be given to the nurse to be used by the physician. all patients are aware of the standard treatment except active treatment group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Clinical trials.gov

Secondary trial Id
NCT03183973

Registration date
2017-07-01, 1396/04/10

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
University street., tabriz., Iran

City
Tabriz

Province
East Azarbaijan

Postal code
98413

Approval date
2017-10-02, 1396/07/10

Ethics committee reference number
IR.TBZMED.REC.1396.591

Health conditions studied

1

Description of health condition studied
Sternal Wound Repair

ICD-10 code
S22.23XG

ICD-10 code description
Sternal manubrial dissociation, subsequent encounter for fracture with delayed healing

Primary outcomes

1

Description
The bone formation in sternum

Timepoint
post operative- until release from hospitalization up to 1

month

Method of measurement

Cardiothoracic surgeon by assessment of photos which are taken from wound site

Secondary outcomes

1

Description

Scar formation or wound infection

Timepoint

post operative- until release from hospitalization up to 1 month

Method of measurement

by cardiothoracic surgeon and sample bacterial culture

Intervention groups

1

Description

Intervention group: Platelet Rich Fibrin (PFR) group

Category

Treatment - Surgery

2

Description

Control group: placebo group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani hospital; SCARM

Full name of responsible person

Peyman keyhanvar

Street address

university Street., Shahid Madani hospital

City

Tabriz

Province

East Azarbaijan

Postal code

98413

Phone

+98 41 3334 9525

Email

drkeyhanvar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ahmad Reza Jodati

Street address

University St.,

City

Tabriz

Province

East Azarbaijan

Postal code

98413

Phone

+98 41 3334 9525

Fax

Email

drkeyhanvar@gmail.com

Web page address

http://scarm.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ahmad Reza Jodati

Position

associated professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

University st., Madani hospital

City

Tabriz

Province

East Azarbaijan

Postal code

98413

Phone

+98 41333349525

Email

Jodati@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Ahmad Reza Jodati

Position
associated professor

Latest degree
Specialist

Other areas of specialty/work
Cardiology

Street address
University st., Madani hospital

City
Tabriz

Province
East Azarbaijan

Postal code
98413

Phone
+98 41333349525

Email
Jodati@tbzmed.ac.ir

Web page address
http://scarm.ir/

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Peyman Keyhanvar

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Medical Nanotechnology

Street address
University st., Madani Hospital

City
Tabriz

Province
East Azarbaijan

Postal code
98413

Phone
+98 41333349525

Email
drkeyhanvar@gmail.com

Web page address
http://scarm.ir/

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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is 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
Share with other studies and collaborate with other research and clinical centers to increase the effectiveness of the study

When the data will become available and for how long
After the study is completed and 6 months after the results are printed

To whom data/document is available
Research Centers and Study Groups of Basic Sciences and Clinical Sciences

Under which criteria data/document could be used
It is possible to use the analyzed results after receiving written permission from the executor

From where data/document is obtainable
Principal Investigator or corresponding author of study

What processes are involved for a request to access data/document
After a written request for the use of results in clinical studies

Comments