

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 (PRF) 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

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Iran (Islamic Republic of)

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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		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.	
Public title	Applicability of Platelet Rich Fibrin (PRF) in closure of non-healing Sternum wound	Placebo	Used
Purpose	Treatment	Assignment	Parallel
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.	Other design features	
Age	From 18 years old to 65 years old	Secondary Ids	
Gender	Both	1	
Phase	2-3	Registry name	Clinical trials.gov
Groups that have been masked	- Participant - Investigator	Secondary trial Id	NCT03183973
Sample size	Target sample size: 10	Registration date	2017-07-01, 1396/04/10
Randomization (investigator's opinion)	Randomized	Ethics committees	
Randomization description	Randomization will take place in base on a restricted, block randomization	1	
Blinding (investigator's opinion)	Double blinded	Ethics committee	
Blinding description	Blind groups will include participating and research groups. In case of blindness, based on a doctor's request,	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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Fax

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Web page address

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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

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Latest degree

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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