Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the efficacy of autologous platelet rich plasma (PRP) in prevention of hypertrophic scar at the site of sternotomy in adults with open heart surgery in Shahid Modarres Hospital in 2020-2021

Protocol summary

Study aim

Determining the efficacy of autologous platelet rich plasma in prevention of hypertrophic scar at the site of sternotomy in adults with open heart surgery

Design

Participants in this study are the adults over 18 years old who undergo open heart surgery in Shahid Modarres Hospital.Each patient on who the intervention is performed will be considered as his control.This study is single-blinded so that the evaluator of the hypertrophic scar's site doesn't know the location of the PRP injection.Based on similar articles, the sample size was calculated 50 people.For sampling, the people who have the inclusion criteria enroll in the study,after signing the informed consent.

Settings and conduct

The study is conducted in Shahid Modarres hospital.The people who undergo open heart surgery and have the inclusion criteria will enroll in the study.Their wound at the site of midsternotomy is divided into two parts.Then, 4 cc of PRP is injected randomly in one part and 4 cc of normal saline as placebo in the other part.The wound site will be evaluated at 2nd,12th and 24th weeks after surgery by a trained personnel who don't know in which part PRP has been injected.

Participants/Inclusion and exclusion criteria

Not having diabetes,autoimmune disease and thrombocytopenia;Not receiving glucocorticoids

Intervention groups

Before the surgery and injection of anesthetics and anticoagulants, a certain volume of blood is taken from the patient .PRP is prepared by an educated person with the help of a standard kit.The midsternal wound is divided into two parts. Randomly, PRP is injected into one half and normal saline solution in the other half as a placebo.Thus every patient is considered as control too. The scar formed at the wound site will be assessed at 2nd, 12th and 24th weeks after the surgery by an educated person not aware of the site of the PRP injection.

Main outcome variables

Hypertrophic scar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201007048955N1**
Registration date: **2020-10-11, 1399/07/20**
Registration timing: **prospective**

Last update: **2020-10-11, 1399/07/20**
Update count: **0**

Registration date

2020-10-11, 1399/07/20

Registrant information

Name

zahra ansari aval

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2208 3095

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z.ansari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the efficacy of autologous platelet rich plasma (PRP) in prevention of hypertrophic scar at the site of sternotomy in adults with open heart surgery in Shahid Modarres Hospital in 2020-2021

Public title
Efficacy of autologous platelet rich plasma (PRP) in prevention of hypertrophic scar
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Not having diabetes Not having autoimmune diseases Not having thrombocytopenia(platelets below 150000) Not receiving glucocorticoids
Exclusion criteria:
Patient not referring to the doctor for surveillance Death of the patient during the surveillance period
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The patients' wound at the site of mid-sternotomy is divided into upper and lower parts, then 4 cc of PRP is randomly injected in one part and 4 cc of normal saline as placebo in the other part. Patients' wounds are then assessed at 2nd, 12th and 24th weeks after surgery by another person who does not know the injection site of PRP and placebo , and the hypertrophic scars in both areas is evaluated by using the Vancouver scar scale(VSS).
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shaheed Beheshti University of Medical Sciences and Health Services, Beside Taleghani Hospital,Tabnak St. , Evin, Shaheed Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-02-26, 1397/12/07
Ethics committee reference number
IR.SBMU.MSP.REC.1397.782

Health conditions studied

1

Description of health condition studied
Keloid and hypertrophic scar
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hypertrophic scar score
Timepoint
2nd, 12th and 24th weeks after surgery
Method of measurement
Vancouver scar scale(VSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before the surgery and injection of anesthetics and anticoagulants, a certain volume of blood is taken from the patient .PRP is prepared by an educated person with the help of a standard kit. The midsternal wound is divided into two parts. Randomly, PRP is injected into one half and normal saline solution in the other half as a placebo. Thus every patient himself is considered as control too. The scar formed at the wound site will be assessed at 2nd, 12th and 24th weeks after the surgery by an educated person not aware of the site

of the PRP injection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarress Educational Hospital

Full name of responsible person

Sadra Ashrafi

Street address

Shahid Modarress Educational Hospital, Saadat Abad St. Yadegare Imam Highway

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Email

modarres@sbmu.ac.ir

Web page address

http://modarres.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Clinical Research Development Center

Full name of responsible person

Naser Malekpour

Street address

Saadatabad intersection, Yadegar Imam Highway, Tehran

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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

Clinical Research Development Center

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sadra Ashrafi

Position

Student of Medical Sciences

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Ansari aval

Position

Deputy Director in education, Research shahid modarres medical center

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact
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Full name of responsible person
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Position
Student of Medical Sciences
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Postal code
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
In order to protect the patients' personal information, the participants' data cannot be revealed.
Study Protocol
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available