Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Assessment the effect of using autologous platelet rich plasma (PRP) in prevention of hypertrophic scar at the site of sternotomy in children with open heart surgery

Protocol summary

Study aim

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

Design

Participants in this study are the children who undergo open heart surgery in Shahid Modarres Hospital.Each patient on this trial will be considered as his control.This study counts as a single-blinded study 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 measured 50 people.For sampling, the people who have the inclusion criteria enroll in the study,after signing the informed consent.

Settings and conduct

The children who undergo open heart surgery in Shahid Modarres hospital and have the inclusion criteria will enroll in the study.Their wound at the site of midsternotomy is divided into two parts.Then, 0.1 cc of prp per 1cm of wound is injected randomly in one part and normal saline as placebo in the other part.The wound site will be assessed at 2nd,12th and 24th weeks after surgery by a trained personnel who don't know location of prp injection

Participants/Inclusion and exclusion criteria

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

Intervention groups

Certain amount of blood in accordance with patient wound length is taken from patient via scalp vein,before using anesthetics and anti coagulants .PRP is prepared by an educated person with the help of centrifuge .The midsternal wound is divided into two parts. PRP is injected into lower half and normal saline solution in the other half as a placebo.Thus every patient is considered as control too. The scar at sternum will be evaluated 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: **IRCT20201007048955N2**
Registration date: **2020-10-31, 1399/08/10**
Registration timing: **prospective**

Last update: **2020-10-31, 1399/08/10**
Update count: **0**

Registration date

2020-10-31, 1399/08/10

Registrant information

Name

zahra ansari aval

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2208 3095

Email address

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

Assessment the effect of using autologous platelet rich plasma (PRP) in prevention of hypertrophic scar at the site of sternotomy in children with open heart surgery

Public title

Assessment the effect of using autologous platelet rich plasma (PRP) in prevention of hypertrophic scar

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Not having diabetes Not having autoimmune disease 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

To **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

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 0.1 cc of PRP per 1 cm of wound length is injected in lower part and 0.1 cc of normal saline per 1 cm of wound length 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

Parallel

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.1397.783

Health conditions studied

1

Description of health condition studied

Hypertrophic scar

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Hypertrophic scar score

Timepoint

2nd, 12th and 24th weeks after surgery

Method of measurement

Based on Vancouver scar scale(VSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Before the induction of surgery and injection of anesthetics and anticoagulants, a certain volume of blood in accordance with patient wound length is taken from the patient .PRP is prepared by an educated person with the help of a centrifuge . The midsternal wound is divided into two parts. PRP is injected into lower 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

2

Description

Control group:Before the induction of surgery and injection of anesthetics and anticoagulants, a certain volume of blood in accordance with patient wound length is taken from the patient .PRP is prepared by an educated person with the help of a centrifuge . The midsternal wound is divided into two parts.Normal saline is injected into Upper half and PRP solution in the other half.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

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Modarress Educational Hospital

Full name of responsible person
Pouya Pourahmad Kisomi

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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Province
Tehran

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1998734383

Phone
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Nassermalekpour@gmail.com

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
Pouya Pourahmad

Position
Student of Medical sciences

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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No 5 , west ghobadiyan Ave ,Alborz St,Mirdamad blv

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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

Name of organization / entity

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Full name of responsible person

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Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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City

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Province

Tehran

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1918944681

Phone

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Email

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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