Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation of the Effects of Platelet-Rich Plasma (PRP) during cesarean section on the integrity and thickness of uterine scar

Protocol summary

Study aim

Evaluation of the Effects of Platelet-Rich Plasma (PRP) during cesarean section on the integrity and thickness of uterine scar

Design

This study is a parallel-group double-blind, randomized controlled trial.

Settings and conduct

The setting of study is two hospitals (Hazrat-e Rasool Akram and firooz Abadi) affiliated to Iran University of Medical of Science. Prior to the intervention informed written consent will be taken. 80 Pregnant women will be randomly divided into two groups (intervention and control) by using computer-generated table of random numbers. In the intervention group, PRP will be directly applied to the uterine myometrium tissue whereas the control group received the usual care.

Participants/Inclusion and exclusion criteria

Pregnant women who are undergoing cesarean section for the first time. Inclusion criteria are: Emergency and non-emergency cesarean section for the first time Exclusion criteria will be: Presence of uterine anomalies with or without previous repair Presence of uterine myoma at the site of caesarean incision History of myomectomy at site of caesarean incision Presence of placenta previa and placenta accrete Prolonged rupture of membranes without chorioamnionitis criteria (consist of fever, uterine tenderness…) Rupture of membranes with chorioamnionitis criteria (consist of fever, uterine tenderness…)

Intervention groups

In the intervention group after the closure of the uterine myometrium incision, PRP will be directly applied to the uterine myometrium tissue whereas the control group received the usual care.

Main outcome variables

The primary outcomes are uterine closure time and primary postpartum hemorrhage. The secondary outcome is to compare the residual myometrial thickness and the depth of cesarean section scar defect after uterine incision closure using the new technique with the conventional technique.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190108042291N1**
Registration date: **2019-01-26, 1397/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-26, 1397/11/06**
Update count: **0**

Registration date

2019-01-26, 1397/11/06

Registrant information

Name

Shahla Mirgaloybayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9283

Email address

mirgaloybayat.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effects of Platelet-Rich Plasma (PRP) during cesarean section on the integrity and thickness of uterine scar

Public title

The Effects of Platelet-Rich Plasma (PRP) during cesarean section on the integrity and thickness of uterine scar.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Emergency and non-emergency cesarean section for the first time

Exclusion criteria:

Presence of uterine anomalies with or without previous repair Presence of uterine myoma at the site of caesarean incision History of myomectomy at site of caesarean incision Presence of placenta previa and placenta accrete Prolonged rupture of membranes without chorioamnionitis criteria (consist of fever, uterine tenderness...) Rupture of membranes with chorioamnionitis criteria (consist of fever, uterine tenderness...)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 80 pregnant women will be divided into two groups of 40 each using a computer-generated table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blinding (blinding participants, and investigators consisting of statistician and specialist in sonography) will be used to reduce the selection bias.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran.

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.IUMS.REC.1397.477

Health conditions studied

1

Description of health condition studied

Cesarean section surgery

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Uterine closure time

Timepoint

During the surgery

Method of measurement

Chronometer

2

Description

Primary postpartum hemorrhage

Timepoint

During and the day after surgery

Method of measurement

Complete Blood Count(CBC)

3

Description

Pain

Timepoint

The day, week and month after surgery

Method of measurement

VAS scale

4

Description
Infection rate
Timepoint
The day, week and month after surgery
Method of measurement
Thermometer

Secondary outcomes

1

Description
Residual myometrial thickness
Timepoint
3 months after the surgery
Method of measurement
Ultrasound examination will be performed 3 months after the operation to assess the integrity of scar by measuring the residual myometrial thickness and the depth of the possible scar defect.

2

Description
The depth of cesarean section scar defect(thickness)
Timepoint
3 months after the surgery
Method of measurement
Ultrasound examination will be performed 3 months after the operation to assess the integrity of scar by measuring the residual myometrial thickness and the depth of the possible scar defect.

Intervention groups

1

Description
Intervention group: In this group, after the closure of the uterine myometrium incision, PRP will be directly applied to the uterine myometrium tissue whereas the control group received the usual care. PRP solution will be prepared based on the following steps: 1. Venous blood (30mL) will be drawn from the patient's arm in anticoagulant-containing tubes; (the recommended temperature during processing is 21℃–24℃ to prevent platelet activation during centrifugation of the blood); 2. The blood will be centrifuged at 1,200 rpm for 12 minutes; 3. The blood separates into three layers: an upper layer that contains platelets and white blood cells, an intermediate thin layer (the buffy coat) that is rich in white blood cells, and a bottom layer that contains red blood cells; 4. The upper and intermediate buffy layers will be transferred to an empty sterile tube. The plasma will be centrifuged again at 3,300 rpm for 7 minutes to help with the formation of soft pellets (erythrocytes and platelets) at the bottom of the tube; 5. The upper two-thirds of the plasma will be discarded because it is platelet-poor plasma.6. Pellets are homogenized in the lower third (5 mL) of the plasma to create the PRP; the PRP will be ready for injection. Approximately 30 mL of venous blood yields 3–5 mL of PRP.7. The prepared PRP solution will be transferred within sterile syringe from the laboratory to the OR 8. Then will be directly applied to the uterine myometrium tissue before skin closure. 9. The patients were examined by the physician on day one, day seven and at day 30 after the procedure.
Category
Treatment - Surgery

2

Description
Control group: In control group cesarean section incision will be closed by the conventional technique(without PRP injection).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Shahla Mirgaloybayat
Street address
Rasoul Akram Hospital, Satarkhan St, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Vice Chancellor for Administration of Iran University of Medical Sciences (IUMS)
Street address
Iran University of Medical Sciences, Hemmat freeway, next to Milad tower, Tehran.
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Email
PR@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Shahla Mirgaloybayat
Position
Assistant professor
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Yes - There is 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
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
There is a plan to make this available.
When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Data will be available for all researchers

Under which criteria data/document could be used

limitless

From where data/document is obtainable

For receiving data please be contacted with mirgaloybayat.sh@iums.ac.ir

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

limitless

Comments