

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the outcome of uterine incision suture with the magon - babo technique (new technique) with the conventional method.

Protocol summary

Study aim

Comparison of the outcome of uterine incision suture with the magon - babo technique (new technique) with the conventional method.

Design

In a randomized clinical trial with the parallel control group, double-blind; Phase 2-3, on 240 patients; randomization is performed by using block randomization

Settings and conduct

In this double-blind clinical trial parallel study, 240 patients who are candidates for cesarean section in Fatemeh Hospital in Hamadan will be included in the study. The researcher who measures and records the consequences and the patients are unaware of the type of intervention performed, so the study is conducted in a double-blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Single pregnancy, Age between 18 and 45 years, Gestational age between 24 and 41 weeks, and history of previous cesarean section Exclusion criteria: Multiple pregnancies, Diabetes, Chronic inflammatory diseases such as lupus, rheumatoid arthritis

Intervention groups

New technique group: After a cesarean section, in patients with chromic suture round 1 of Supa company, the whole layer of the myometrium, the incision site is cut from one centimeter away, and the decidua part is swabbed in both upper and lower parts, and examined for nich lesions. Conventional technique group: The uterus is sutured in two layers, the first layer is lacquered and the second layer is lacquered chrome 1 round without Supa company and are examined for nich lesions

Main outcome variables

Nich, residual myometrial thickness, Spotting, and Pelvic pain 6 & 9 months after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N24**

Registration date: **2022-07-16, 1401/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-16, 1401/04/25**

Update count: **0**

Registration date

2022-07-16, 1401/04/25

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3428 9706

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the outcome of uterine incision suture with the magon - babo technique (new technique) with the conventional method.

Public title

Comparison of the outcome of new method of uterine incision suture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Single pregnancy Age between 18 and 45 years
Gestational age between 24 and 41 weeks history of previous cesarean section

Exclusion criteria:

Multiple pregnancies Diabetes Chronic inflammatory diseases such as lupus, rheumatoid arthritis

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention(new method) and on the other two sheets the name of the control(routine method). The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action is repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher who measures and records the consequences and the patients are not aware of the type of intervention performed, so the study is performed in a double-blinding manner.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-05-07, 1401/02/17

Ethics committee reference number

IR.UMSHA.REC.1401.148

Health conditions studied

1

Description of health condition studied

Maternal care for scar from previous cesarean delivery

ICD-10 code

O34.21

ICD-10 code description

Maternal care for scar from previous cesarean delivery

Primary outcomes

1

Description

Nich

Timepoint

6 & 9 months after cesarean section

Method of measurement

Based on ultrasound findings (yes / no)

Secondary outcomes

1

Description

Residual myometrial thickness

Timepoint

6 & 9 months after cesarean section

Method of measurement

Based on ultrasound findings (mm)

2

Description

Pelvic pain

Timepoint

6 & 9 months after cesarean section

Method of measurement

Asking from patient (Visual Analogue Scale)

Intervention groups

1

Description

New technique group: After cesarean section, in patients with chromic suture round 1 of Supa company, the whole layer of the myometrium, the incision site is cut from one centimeter away, and the decidua part is swabbed in both upper and lower parts.

Category

Treatment - Surgery

2

Description

Conventional technique group: The uterus is sutured in two layers, the first layer is lacquered and the second layer is lacquered chrome 1 round without Supa company.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Shahla Nasrolahi

Street address

Fatemieh Hospital, Pasdaran Ave.

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6517838695

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Dr-nasrolahi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohei

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Hamadan University of Medical Sciences, Shahid
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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Shahla Nasrolahi

Position

Associate Professor of Perinatology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Neda shafie

Position

Resident Gynecology and Obstetrics

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

No - There is not a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available