

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Clinical trial of the effect of amniotic membrane on post cesarean pain

Protocol summary

Summary

Objective: to investigate the effect of amniotic membrane dressing on the pain after Caesarean section. Study design: a randomized double blind clinical trial study. Population: 90 mothers undergoing caesarean section are enrolled in the study. Inclusion criteria: gestational age between 38 and 42 weeks, willingness to participate in the study, experiencing the first cesarean section, live and singleton pregnancy, not having any kind of previous surgery, not smoking or consuming alcohol and drugs, no history of known diseases (such as liver and kidney dysfunction, cardiovascular, respiratory, and neuromuscular diseases, diabetes, and hypertension), and undergoing general anesthesia. Exclusion criteria: the surgery last for more than 90 minutes, the patients do not cooperate in measuring and recording the pain level. Patients will be divided into two groups of 45. In the intervention group after removal of the placenta, the fetal amniotic membrane is separated from the placenta. The membrane is placed as double-layered on the sutured wound. The intended intervention is applied immediately after suturing, remaining on the wound until the removal of stitches (24 hours). In the control group, routine dressing is performed by putting dry sterile gauze on the wound. Pain severity would be measured, recorded, and compared between two groups in 4, 12, 24, 36, and 48 hours after surgery by Visual Analogue Scale (VAS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040516110N3**
Registration date: **2016-06-30, 1395/04/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-30, 1395/04/10

Registrant information

Name

Fatemeh Mohseni

Name of organization / entity

Shiraz University of Medical Sciences, Nursing & Midwifery Faculty

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Gerash University of Medical Sciences

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2016-08-31, 1395/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of amniotic membrane on post cesarean pain

Public title

The effect of amniotic membrane on post cesarean pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: gestational age between 38 and 42 weeks, willingness to participate in the study,

experiencing the first cesarean section, live and singleton pregnancy, not having any kind of previous surgery, not smoking or consuming alcohol and drugs, no history of known diseases (such as liver and kidney dysfunction, cardiovascular, respiratory, and neuromuscular diseases, diabetes, and hypertension), and undergoing general anesthesia. exclusion criteria: the surgery last for more than 90 minutes, the patients do not cooperate in measuring and recording the pain level

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 90

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
block randomization method. The patients and the researcher that will assess the pain, will be blind to the kind of intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gerash University of Medical Sciences

Street address

Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran

City

Gerash

Postal code

58666 - 74417

Approval date

2016-03-05, 1394/12/15

Ethics committee reference number

IR.GERUMS.REC.1394.1014

Health conditions studied

1

Description of health condition studied

caesarean section

ICD-10 code

o82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

pain

Timepoint

4, 12, 24, 36, 48 hrs after caesarean

Method of measurement

VAS

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Interventional group: in the intervention group after removal of the placenta, the fetal amniotic membrane is separated from the placenta by a gynecologist surgeon. The membrane is placed as double-layered on the sutured wound. The intended intervention is applied immediately after suturing, remaining on the wound until the removal of stitches (24 hours).

Category

Other

2

Description

Control group: In the control group, routine dressing is performed by putting dry sterile gauze on the wound.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gerash Amir-al-Momenin medical and educational center

Full name of responsible person

Fatemeh Mohseni

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Gerash Amir-al-Momenin medical and educational center, Vahdat street, Shahid beheshti square, Gerash, Fars province , Iran.

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Gerash University of Medical Sciences

Full name of responsible person

Afsaneh Besharati

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City

Gerash

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Gerash University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Gerash Amir-al-Momenin medical and educational center

Full name of responsible person

Fatemeh Mohseni

Position

Master of science nursing

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty*

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty