Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 duble 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, Nnursing & Midwifery Faculty

Country
Iran (Islamic Republic of)

Phone
+98 71 1647 4254

Email address
mohseni_f@sums.ac.ir

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

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
Street address
Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran
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
Gerash Amir-al-Momenin medical and educational center, Vahdat street, Shahid beheshti square, Gerash, Fars province , Iran.
City
Gerash
Postal code
Phone
+98 71 5244 2003
Fax
Email
mohseni@gerums.ac.ir; mohseni0489@gmail.com
Web page address

Person responsible for scientific 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
Gerash Amir-al-Momenin medical and educational center, Vahdat street, Shahid beheshti square, Gerash, Fars province , Iran.
City
Gerash
Postal code
Phone
+98 71 5744 2002
Fax
Email
mohseni@gerums.ac.ir; mohseni0489@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Gerash Amir-al-Momenin medical and educational center, Gerash, Fars, Iran
Full name of responsible person
Fatemeh Mohseni
Position
Master of science nursing
Other areas of specialty/work
Street address
Gerash Amir-al-Momenin medical and educational center, Vahdat street, Shahid beheshti square, Gerash, Fars province , Iran.
City
Gerash
Postal code
Phone
+98 71 5245 0489
Fax
Email
mohseni@gerums.ac.ir; mohseni0489@gmail.com
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