

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of amniotic membrane on cesarean wound healing in womans who refered to gerash medical and educational center in 2014

Protocol summary

Summary

Objective: To determine the effect of dressing by amniotic membrane on the cesarean wound healing.

Methods: This study is a prospective randomized double-blind clinical trial. Patients participating in the study were women who undergoing cesarean section in Amir-al-Momenin hospital of Gerash, Iran. The inclusion criteria include: (1) Term pregnancy (42-37 weeks), (2) Body mass index (BMI) greater than 29, (3) Willingness to participate in the study, (4) No complications of pregnancy (eclampsia, placenta previa, placenta abruption, multiple birth, Corioamniotitis, meconium defecation, poly Hydroamnios), (5) No history of any known disease with affect to wound healing, (6) Not having any Abnrmlality in the fetus and infants hospitalized to the NICU, (7) No major bleeding or need for blood transfusion, hysterectomy or myomectomy, (8) No smoking, alcohol and drugs, (9) No preoperative rupture of membrane, (10) The lack of meconium defecation, (11) No history of cesarean section more than two time. Women were excluded from the study if: the operation prolonged for more than 90 minutes, or patient did not refer to the hospital 8 days after surgery. Patients were divided into two groups (N=45 for each group). In one group, the wound was dressing by amniotic membrane and in the control group dressing was done by simple dressing. The wound healing was assessed by REEDA scale 24 hours and 8 days after cesarean.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010616110N1**

Registration date: **2014-04-30, 1393/02/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-30, 1393/02/10

Registrant information

Name

Fatemeh Mohseni

Name of organization / entity

Shiraz University of Medical Sciences, Nnursing & Midwifery Faculty

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Phone

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Recruitment status

Recruitment complete

Funding source

shiraz university of medical sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-06-05, 1393/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of amniotic membrane on cesarean wound healing in womans who refered to gerash medical and educational center in 2014

Public title

The effect of amniotic membrane on cesarean wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: term pregnancy (42-37 weeks); Body mass index (BMI) greater than 29; willingness to participate in the study; no complications of pregnancy (eclampsia, placenta previa, placental abruption, twin pregnancy, Corioamniotitis, meconium defecation, poly Hydroamnios); no history of any known disease with affect to wound healing; not having any abnormality in the fetus and infants hospitalized to the NICU; no major bleeding or need for blood transfusion, hysterectomy or myomectomy; no smoking, alcohol and drugs; no rupture of membrane; the lack of meconium defecation; no history of cesarean section more than two time.

Exclusion criteria: prolonged operation for more than 90 minutes; no referral 8 days after surgery.

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand street,shiraz

City

Shiraz

Postal code

14336 - 71348

Approval date

2014-04-15, 1393/01/26

Ethics committee reference number

93-6993

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Wound healing

Timepoint

24 hours after intervention and 8 day after intervention

Method of measurement

REEDA scale

Secondary outcomes

empty

Intervention groups

1

Description

In this procedure, the amniotic membrane was separated from placenta using of sterile gloves by gynecologist. Thus after washing with normal saline and cleaning membrane from blood and clot, the amniotic membrane was placed on the wound of surgery in the experimental groups. To prevent rapid drying of membrane a wet sterile gauze with saline was placed on it and then wound was dressed by a few dry gauze.

Category

Treatment - Other

2

Description

In the control group dressing was done by dry gauze.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-al-Momenin Gerash Medical and Educational Center

Full name of responsible person

Mohseni Fatemeh

Street address

amir-al-momenin medical and educational center,emam khomeini street,gerash,fars

City
Gerash

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seied Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand street,shiraz

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Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Molazem Zahra

Position

assistant professor

Other areas of specialty/work

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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