

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Effect of Amniotic membrane graft of the fetal membrane on pain, infection, and repair of large episiotomy

Protocol summary

Study aim

Evaluation of the effect of amniotic layer transplantation of embryonic membranes on pain, infection, repair and opening of large episiotomies

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. Excel software rand function was used for randomization

Settings and conduct

Umm Al-Banin Hospital in Mashhad In this project, healthy women who have given birth have been expanded for episiotomy (ie the length of the site in the vaginal mucosa is more than 5 cm and the depth of the episiotomy site is more than 3 cm. The study method and its objectives and obtaining the consent of the participants in the study are included in the plan. To hide the allocation, closed-door envelopes are used.

Participants/Inclusion and exclusion criteria

Healthy women without specific diseases Absence of fever and infection during childbirth Need an episiotomy to deliver Exclusion criteria: Use of instrumental delivery, Prolonged rupture of the bladder Long hospital stay longer than 24 hours Multiple examinations and fever

Intervention groups

Intervention group: Newly delivered women will need an amniotic layer transplant for fetal membranes with the need for an episiotomy for labor whose episiotomy has been expanded. Control group (s) Newly delivered women will need an episiotomy to give birth if their episiotomy is enlarged and they will be given routine treatment.

Main outcome variables

Pain intensity at the episiotomy repair site using a pain ruler for up to 24 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N54**

Registration date: **2022-07-03, 1401/04/12**

Registration timing: **prospective**

Last update: **2022-07-03, 1401/04/12**

Update count: **0**

Registration date

2022-07-03, 1401/04/12

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

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

The Effect of Amniotic membrane graft of the fetal membrane on pain, infection, and repair of large

episiotomy	
Public title	The Effect of Amniotic membrane graft of the fetal membrane on pain
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Having informed consent to participate in the study Healthy women without specific diseases Absence of fever and infection during childbirth Need an episiotomy to deliver Expansion of the episiotomy Exclusion criteria: Use of instrumental delivery Prolonged rupture of the bladder Multiple examinations and fever Long hospital stay longer than 24 hours Withdrawal from study during childbirth Failure to refer to postpartum care are among the factors excluded from the study
Age	No age limit
Gender	Female
Phase	3
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, permutation block method was used to generate a sequence of random allocation of individuals to the study groups. Random allocation sequence was performed using random allocation software and block size four. The permutation block method is one of the random allocation methods in which each block is selected according to the number of groups studied.
Blinding (investigator's opinion)	Double blinded
Blinding description	Closed-door envelopes are used to conceal the allocation. According to the order of arrival of the research units, the envelopes are opened in order and the assigned group is revealed.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Mashhad University of Medical Science
Street address	Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City	Mashhad
Province	Razavi Khorasan
Postal code	12345
Approval date	2022-05-30, 1401/03/09
Ethics committee reference number	IR.MUMS.MEDICAL.REC.1401.039
Health conditions studied	
<u>1</u>	
Description of health condition studied	Complications of labour and delivery
ICD-10 code	
ICD-10 code description	Complications of labour and delivery Perineal laceration during delivery
Primary outcomes	
<u>1</u>	
Description	Severe pain at the site of episiotomy repair
Timepoint	Up to 24 hours after the intervention
Method of measurement	Using a pain ruler
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: Newly delivered women will need an amniotic membrane transplant for fetuses who need an enlarged episiotomy to give birth.
Category	Treatment - Other
<u>2</u>	
Description	Control group: Newly delivered women will need to undergo an episiotomy for labor whose episiotomy has

been expanded and will undergo routine treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommolbanin Hospital

Full name of responsible person

Farideh Akhlaghi

Street address

Razavi Khorasan Province, Mashhad, Ayatollah Bahjat St,

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Postal code

91447 34756

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Email

AkhlaghiF@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Farideh Akhlaghi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Email

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available