

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of perineum warm pad in the second stage of labour on episiotomy and genital tract trauma rate

Protocol summary

Summary

The aim of this randomized clinical trial study is to determine the effect of perineum warm pad on episiotomy and genital tract trauma rate in nulliparous women. Inclusion criteria: The mother age between 18_35 years; fetal birth weight in normal range; singleton pregnancy and cephalic presentation; gestational age between 37_42 weeks. The exclusion criteria: creating any contraindication for continuing normal delivery and needing cesarean section and instrumental delivery. The study population includes 114 nulliparous women will be randomly selected as the sample. The case and control groups contain 57 subject each. In this study there is no any intervention in labour and delivery process in control group but for case group the warm pad is placed on the mothers perineum by trained midwives at the start of second stage of labour. The pad will be removed when the mother is transferred to the delivery room. The researcher which is the delivery agent is unaware of setting and unsetting the pad to every one of the mothers. Sampling is continually during 3 months and 3 or 4 times a week. The first sign of research is the effect the warm pad of episiotomy and genital tract trauma rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101519547N1**
Registration date: **2015-05-17, 1394/02/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-17, 1394/02/27

Registrant information

Name

Fatemeh Alihosseini

Name of organization / entity

Ahvaz uni of medical science

Country

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2015-03-16, 1393/12/25

Expected recruitment end date

2015-06-15, 1394/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of perineum warm pad in the second stage of labour on episiotomy and genital tract trauma rate

Public title

The effect of perineum warm pad in the second stage of labour on episiotomy and genital tract trauma rate

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The mother age 18_35; The gestational age 37_42 weeks; normal fetal birth range 2500_4000gr; singleton pregnancy & cephalic presentation; no any contraindication for normal delivery at the beginning of

admission. Exclusion criteria: Creating any contraindication for continuing normal delivery during study and needing cesarean section; creating any dystotia during delivery; needing instrumental delivery.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz University Of Medical Sciences

Street address

Golestan Autobahn

City

Ahvaz

Postal code

61357_15794

Approval date

2014-09-06, 1393/06/15

Ethics committee reference number

ajums.rec.1393.186

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Number of episiotomies

Timepoint

After delivery

Method of measurement

Observation and count

2

Description

Number of prineal tears

Timepoint

After delivery

Method of measurement

Observation and count

Secondary outcomes

empty

Intervention groups

1

Description

In case group: using the warm pad during the second stage of labour at the start of which the warm pad is placed on mother perineum. This pad can produce about 45C heat for at most 12 hours.

Category

Prevention

2

Description

In control group: Doing routine cares in the ward without using placebo.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital of Andimeshk

Full name of responsible person

Fatemeh Alihosseini

Street address

Emam Ali hospital, Emam Ali autoban, Andimeshk, Khoozestan

City

Andimeshk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Naser Saki

Street address

Golestan autobahn, Ahvaz, Khoozestan

City

Ahvaz

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

Yes

Title of funding source

Ahvaz 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**

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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