

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Influence of warm compress bi-stage intervention on prevention of perineal trauma and second stage pain intensity and duration the first stage and second stage in primiparous with delayed valsalva maneuver referred to selected hospital of Shiraz university of medical science 91

Protocol summary

Summary

Purpose: introduce intentional and non-intentional injuries present a method for preventing and reducing perineal pain during the second stage of labor. Study is a randomized clinical trial. After visiting the hospital authorities to allow the written satisfaction of the people participating in the project, 75 people in two separate groups experience and Inclusion criteria: gestational age 37-42 weeks; primiparous; Oa; single fetus; show vertex; no cpd; no history of any medical condition and no risk of preeclampsia. Exclusion criteria: use of forceps or vacuum and prolonged second stage of delivery more than 2 hours. For control group is take in the routine care and in experience group when the cervix was dilated 7 cm from the warm compress and we use when Full cervical dilatation was opened in the spine when the cervix was fully dilated descent of fetal head and spine area was warm compresses can be used prior to the boiling water is heated to 70 degrees warm compresses placed inside a sterile towel and 15-20 minutes for women in labor can be placed on the perineal and warm compresses should be 37-40 degrees temperature and she is asked no to force, then the postpartum perineal injury severity pain rate of delivery and using Mc Gill and check list is investigated. After entering the information with software spss statistical analysis of the formulations are used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012111211422N1**

Registration date: **2013-03-16, 1391/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-16, 1391/12/26

Registrant information

Name

Mahnaz Farahmand

Name of organization / entity

Shiraz University of Medical Sciences

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+98 71 1627 9131

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farahmm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-08-10, 1391/05/20

Expected recruitment end date

2012-11-30, 1391/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence of warm compress bi-stage intervention on prevention of perineal trauma and second stage pain intensity and duration the first stage and second stage in primiparous with delayed valsalva maneuver referred to selected hospital of Shiraz university of medical science

Public title

Warm compress on the injury severity of perinea pain in labor

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 37-42 weeks; primiparous; OA; single fetus; show vertex; no cpd; no history of any medical condition and no risk of preeclampsia Exclusion criteria: use of forceps or vacuum and prolonged second stage of delivery more than 2 hours.

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: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not 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

zand street

City

Shiraz

Postal code

719351314

Approval date

2012-10-07, 1391/07/16

Ethics committee reference number

CT-91-6272

Health conditions studied**1****Description of health condition studied**

Childbirth

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vaginal delivery

Primary outcomes**1****Description**

Perineal trauma

Timepoint

Immediatly after childbirth

Method of measurement

Chek list

2**Description**

The intensity of pain in second stage of labour

Timepoint

One hour after delivery

Method of measurement

McGill ruler

Secondary outcomes**1****Description**

The lenght of rupture

Timepoint

After childbirth

Method of measurement

Meter

2**Description**

Intensity of pain

Timepoint

One hour after delivery

Method of measurement

McGill ruler

Intervention groups**1****Description**

control:Routine care

Category

Prevention

2**Description**

I ntervention group: when the cervix was dilated 7 cm

from the warm compress and we use when Full cervical dilatation was opened in the spine. As a result, fetal head intervention was to use hot compresses on the perineum is used for 15-20 minutes and the Valsalva maneuver may delay

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

shoshtari hospital

Full name of responsible person

Akbarzadeh marzieh

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Namazi square

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2**Recruitment center****Name of recruitment center**

Hazrat zynab hospital

Full name of responsible person

Akbarzadeh marzieh

Street address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Gholamreza Hatam

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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

Vice chancellor for research, 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

Akbarzadeh

Position

Ms in midwifery

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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