

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

The effect 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 sciences 2012

Protocol summary

Summary

This study is a randomized clinical trial on 255 women referred to the maternity hospital in Shiraz University of Medical Sciences and considering the effect 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. After obtaining informed consent, the eligible women were randomly allocated into three groups (two experimental groups and one control group). In three groups to measure the second stage of labor pain using the McGill Pain ruler was used and valsalva maneuver to decrease until there is a feeling of straining itself, was postponed. In two groups, warm compresses between 15-20 minutes and during contractions were laid on perineal. Groups with a single step, after entering the second stage of labor (dilation 10 centimeters and a zero position) were put warm compresses on the perineum. The two-stage intervention group, a warm compress on the dilatation of 7-8 cm and a lateral dilatation of 10 cm was placed on the perineum. The control group received only routine care. All samples were delivered in position lithotomy position. Postpartum (Stage IV) in all three groups already prepared a questionnaire to determine the action episiotomy, perineal intact, rupture length, rupture area, was completed. .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051511706N7**

Registration date: **2014-05-17, 1393/02/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-17, 1393/02/27

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Council of Shiraz University of Medical Sciences

Expected recruitment start date

2012-10-11, 1391/07/20

Expected recruitment end date

2013-01-09, 1391/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect 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 sciences

2012	
Public title	Postal code 71345-1978
The effect 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	Approval date 2012-08-31, 1391/06/10
Purpose	Ethics committee reference number CT_P_6272
Supportive	
Inclusion/Exclusion criteria	Health conditions studied
The inclusion criteria: primiparous; single and term pregnancy; vertex presentation; lack of hip tightness; no previous exposure to any type of medical condition; no preeclampsia; mother's age 18-35 years old; Hb≥11; lack of any lesion in the perineum and vagina; 2000-3500 gr birth weight; anterior oxypot; not using local anesthesia and analgesia techniques such as gas Entonox; no method of perineal massage during pregnancy. The exclusion criteria: any condition requiring induction of labor or cesarean section, such as placental abruption, meconium, fetal distress in the first and second stage; the use of forceps or vacuum extraction; prolonged second stage more than 2 hours.	1
Age	Description of health condition studied Pain intensity
From 18 years old to 35 years old	ICD-10 code R10
Gender	ICD-10 code description Abdominal and pelvic pain
Female	
Phase	2
N/A	Description of health condition studied Perineal laceration
Groups that have been masked	ICD-10 code O70
No information	ICD-10 code description Perineal laceration during delivery
Sample size	Primary outcomes
Target sample size: 225	1
Randomization (investigator's opinion)	Description Second stage of labor pain
Randomized	Timepoint After delivery
Randomization description	Method of measurement McGill Pain ruler
Blinding (investigator's opinion)	
Not blinded	2
Blinding description	Description Perineal laceration size
Placebo	Timepoint After delivery
Not used	Method of measurement Sterile meter
Assignment	
Parallel	Secondary outcomes
Other design features	empty
Secondary Ids	
empty	
Ethics committees	
1	Intervention groups
Ethics committee	1
Name of ethics committee	Description Groups with a single step, after entering the second stage of labor (dilation 10 centimeters and a zero position) were put warm compresses for 20-15 minutes in between and during contractions on the perineum.
Ethics in Medical Research, Shiraz University of Medical Sciences	Category Other
Street address	
Deputy of Research_Floor 7_University of Medical Sciences of Central Building_Zand Avenue_Shiraz	
City	
Shiraz	

2

Description

The two-stage intervention group, a warm compress on the cervix dilatation 8-7 cm and a 10 cm between and during contractions lasting 20-15 minutes on the perineum was placed.

Category

Other

3

Description

The control group received only routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shushtari Hospital

Full name of responsible person

Andishe Jorkesh

Street address

Corner Regiment - Shushtari Hospital

City

Shiraz

2

Recruitment center

Name of recruitment center

Hafez hospital

Full name of responsible person

Dr Marya Yazdani

Street address

Beginning Chamran Boulevard

City

Shiraz

3

Recruitment center

Name of recruitment center

Hazrat Zeinab Hospital

Full name of responsible person

Mahboobe Hatam

Street address

Ghods square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Research_seven floors_University of Central Building_
near red crescent_zand avenue

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of 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

Faride Vaziri

Position

Master of Midwifery, Faculty Member

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work**Street address**

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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