Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of hot bag water and eflorage massage in active phase of labor, on Pain severity in primiparous women

Protocol summary

Summary
The aim of study: Comparisonthe effect of hot bag water and eflorage massage in active phase of labor, on Pain severity in primiparous women. A Randomized(The use of sealed envelopes); not blinded, controlled, single-center, phase two trial. Inclusion criteria: the prediction of vaginal delivery with a normal history and physical examination by a medical team. . Exclusion criteria: Any reasons during the Labour, Start out of the labor and requiring special care or having an emergency cesarean section, Sensitivity to oil, Unwillingness to continue participation in the study. Sample size: 90. Type of Intervention:hot bag water, eflorage massage. Time involved: the active phase of labor and transitional. outcomes: reducing labor pain.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2015090615338N3**
Registration date: **2015-10-19, 1394/07/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2015-10-19, 1394/07/27

Registrant information
Name
Shahnaz Golian Tehrani
Name of organization / entity
Nursing and Midwifery faculity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Science

Expected recruitment start date
2015-09-23, 1394/07/01
Expected recruitment end date
2015-12-22, 1394/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of hot bag water and eflorage massage in active phase of labor, on Pain severity in primiparous women

Public title
reducing labor pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: primiparous women with physical and mental health patients in the active phase; the prediction of vaginal delivery with a normal history and physical examination by a medical team; The Midwifery no problems in accepting the views of abnormal embryos, multiple pregnancies, fetal macrosomia, and pelvic disproportion, polyhydramnios, olygohydramnios, preeclampsia, premature placental separation, placenta previa, fast delivery and uterine infections; with a singleton pregnancy, cephalic view; no risk of hypertension, diabetes and other medical disorders in pregnancy; No risk of skin diseases like eczema, and any wound in the hot bag and massage; Having spontaneous

contractions. Exclusion criteria: All mothers of the natural course of maternal or fetal Labor Start due to factors such as detachment, cord prolapse, fetal distress out or for any reason during the Labor Start out of the labor and require special care or have an emergency cesarean section; Lack of desire to continue participating in the study; Use of drugs such as oxytocin labor catalyst; Use of an analgesic such as pethidine.

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Tehran University of Medical Science

Secondary Ids

1

Registry name
golian

Secondary trial Id
46po

Registration date
1394-07-02, 777/01/-1356

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Central apartment of Tehran University of Medical Sciences, Keshavarz blvd

City
Tehran

Postal code

Approval date
2014-06-30, 1393/04/09

Ethics committee reference number
1525/130/d/93

Health conditions studied

1

Description of health condition studied
delivery

ICD-10 code
O00-O99

ICD-10 code description
Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description
Pain

Timepoint
Every 30 minutes

Method of measurement
Visual analogue of pain

Secondary outcomes

empty

Intervention groups

1

Description
Group 1:hot water bag for 15 minutes

Category
Other

2

Description
Group 2: eflorage massage for 20 minutes

Category
Other

3

Description
Control group: routine delivery room care

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive women's hospital

Full name of responsible person
Zahra Kohzad

Street address
Karimkhan Zand Street, Nejatollahi Street,Comprehensive women's hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Science research
Full name of responsible person
Dr. Masood Younesian
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Central Building of Tehran University of Medical Sciences, the Qods Street, Keshavarz Blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Science research
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

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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