Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effect of Hot Water Bag and Hot Water Shower on the Pain and Active Phase of Pregnancy in Primiparous Women

Protocol summary

Study aim

Comparison of the effect of warm water bag and hot water shower on pain and duration of first stage of labor in primipara women

Design

The study consisted of two groups of 36 people (warm water bag, warm shower) that were randomly divided into two groups.

Settings and conduct

This study is done in delivery unit of Shahidan Mobini hospital in Sabzevar. Mothers, after obtaining informed consent and having the conditions for entering the study, are placed in two groups of hot water and warm water showers. After receiving the intervention, the pain and duration of maternal delivery are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age between 37 and 42 weeks, First pregnancy, The spontaneous onset of labor pains, No record of mental and medical sickness, Normal heart rate of fetus, Single pregnancy, No addiction to cigarette, drugs, and alcohol, Having no detectable barriers to normal delivery, No record of infertility
Exclusion criteria: Having contraindications to normal delivery, Consumption of any tranquilizer or drug within 48 hours before the start of the study

Intervention groups

In the warm shower group:, warm shower is performed in 4 cm of dilatation , and the researcher is assisted by a full body shower for 15 minutes in a 7 cm dilatation. In the hot water bag in the active phase of labor (4 centimeters up) and once in a 7-cm stage, a warm water bag is in the waist, fundus, or under the abdomen. The duration of using a warm water bag is based on the book of principles and techniques of nursing every 20 minutes.

Main outcome variables

Active phase length of labor Labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151005024371N3**
Registration date: **2019-02-05, 1397/11/16**
Registration timing: **retrospective**

Last update: **2019-02-05, 1397/11/16**
Update count: **0**

Registration date

2019-02-05, 1397/11/16

Registrant information

Name
Mozhdeh Navi Nezhad

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 51 4423 3808

Email address
navinm921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effect of Hot Water Bag and Hot Water Shower on the Pain and Active Phase of Pregnancy in Primiparous Women

Public title
Comparison of the Effect of Hot Water Bag and Hot Water Shower on the Pain and Active Phase of Pregnancy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age between 37 and 42 weeks First pregnancy The spontaneous onset of labor pains No record of mental and medical sickness Normal heart rate of fetus Single pregnancy No addiction to cigarette, drugs, and alcohol Having no detectable barriers to normal delivery No record of infertility
Exclusion criteria:
Problems and skin ulcers Consumption of any tranquilizer or drug within 48 hours before the start of the study Mother's lack of cooperation

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: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling method: Using random allocation using variable blocks.Two groups of four blocks (AABB-BBAA-ABAB-BABA-ABBA-BAAB) were used. The subjects were divided into two groups of intervention and control in order to determine the number of subjects in equal groups (36 in each group). Control group A and intervention group B were called. To determine the order of entry of individuals into groups, random numbers and closed packet were used.

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
Sabzevar Medical Sciences

Street address
Kashfi Street

City
Khorasan Razavi

Province
Razavi Khorasan

Postal code
9613883778

Approval date
2018-08-21, 1397/05/30

Ethics committee reference number
IR.MEDSAB.REC.1397.026

Health conditions studied

1

Description of health condition studied
Natural delivery

ICD-10 code
O75.0

ICD-10 code description
Maternal distress during labour and delivery

Primary outcomes

1

Description
Labor pain severity

Timepoint
Before intervention and 30 minutes after intervention

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Duration of active phase of labor

Timepoint
From 4 cm dilation to full dilation

Method of measurement
Partograph form in terms of minute

Intervention groups

1

Description
"Hot water shower group": Hot shower will be firstly applied for 20 minutes at 4 cm dilation and then at 7 cm dilation. Main outcome measures include the pain severity and the duration of active phase that will be measured respectively by Visual Analogue Scale (VAS) and partograph form.

Category
Treatment - Other

2

Description
"Warm water bag group":Warm water bag will be firstly applied for 20 will be firstly applied for 20 minutes at 4 cm dilation and then at 7 cm dilation. Warm water bag will be used in the waist, fundus or abdomen.Main outcome measures include the pain severity and the duration of active phase that will be measured respectively by Visual Analogue Scale (VAS) and partograph form.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mobini hospital
Full name of responsible person
Mitra Eftekhar Yazdi
Street address
Kashfi Street
City
Sabzevar
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9613883778
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mitra Eftekhar YAZDI
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City
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Province
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Phone
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Email
navinm921@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Sabzevar 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

2

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
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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
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Mitra Eftekhar Yazdi
Position
Expert physician
Latest degree

Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
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Position
Above specialization
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sabzevar University of Medical Sciences
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Above specialization
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data relating to the main variables of the research is reported after being unidentifiable
When the data will become available and for how long
The beginning of the access period is 6 months after the publication of the article
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Registered at the Clinical Practice Registration Center
From where data/document is obtainable
Responsible for studying Contact with mailbox NAVINM921@MUMS.AC.IR
What processes are involved for a request to access data/document
Send an email requesting data to the study author by email NAVINM921@MUMS.AC.IR
Comments