Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison effect of rosewater and placebo on reducing labor pain in primiporous women

Protocol summary

Summary

Aim: The effect of rosewater aromatherapy on reducing labor pain in primiparous women Inclusion criteria: Nulliparous women, Gestational age of 37 weeks until 42 weeks, Singleton Exclusion criteria: Using other methods of pain relief during the study, Labor complications after intervention, Patient intolerance The study population: The nulliparous women in 38-42 weeks pregnancy that admitted to Arak´s Taleghani Hospital for vaginal delivery The sample size: One hundred and eleven nulliparous women including 1- Rosewater (N=37) 2- placebo (N=37) and 3- control (N=37) group Intervention: Women randomly were divided to three groups, including rosewater, placebo (water) and negative control group. In initial study (5-4 cm dilation) labor pain intensity was determined by pain visual analogue scale. Then the client was asked to inhale rosewater or placebo in dilatation of 5-7 and 8-10 cm. In control group, routine care was conducted by the researcher assistant Pain intensity was measured before and 30 minutes after intervention and also dilatation of 10 cm. Outcome: labor pain intensity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110914450N3**
Registration date: **2014-12-22, 1393/10/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-22, 1393/10/01

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Arak University of Medical Sciences

Expected recruitment start date

2012-02-13, 1390/11/24

Expected recruitment end date

2013-01-18, 1391/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of rosewater and placebo on reducing labor pain in primiporous women

Public title

The effect of rose water aromatherapy on reducing labor pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Nulliparous women; Gestational age of 37 weeks until 42 weeks; Singleton; Cephalic presentation; 4 to 5 cm dilation Exclusion criteria: Using other methods of pain relief during the study; Labor complications after intervention; Patient intolerance

Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **111**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of medical sciences
Street address
Arak University of Medical Sciences, Pardis Danshgae, Basij square, Arak, Iran
City
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Postal code
6941-7-38481
Approval date
2009-02-19, 1387/12/01
Ethics committee reference number
24-1-87

Health conditions studied

1

Description of health condition studied
labor pain
ICD-10 code
080.0
ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
severity Labor pain
Timepoint
before and 30 min after intervention
Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In initial study (5-4 cm dilation) labor pain intensity was determined by pain visual analogue scale. Then the client was asked to inhale rosewater in dilatation of 5-7 and 8-10 cm. Pain intensity was measured before and 30 minutes after intervention and also dilatation of 10 cm.
Category
Treatment - Drugs

2

Description
Placebo group: In initial study (5-4 cm dilation) labor pain intensity was determined by pain visual analogue scale. Then the client was asked to inhale water (placebo) in dilatation of 5-7 and 8-10 cm. Pain intensity was measured before and 30 minutes after intervention and also dilatation of 10 cm.
Category
Placebo

3

Description
Control group: In initial study (5-4 cm dilation) labor pain intensity was determined by pain visual analogue scale. Routine care was conducted by the researcher assistant. Pain intensity was measured in dilatation of 5-7 and 8-10 cm and 30 minutes later and also dilatation of 10 cm.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Dr. Nasrin Roozbahani
Street address
Ayatollah Taleghani Hospital, Imam khomeini street, Arak, Iran
City

Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Arak University of Medical Sciences
Full name of responsible person
Dr. Aliasgar Yagobi
Street address
Arak University of Medical Sciences, Pardis Danshgae, Basij square, Arak, Iran
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Arak
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 of Arak 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
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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