

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 primiporous 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

Name

Nasrin Roozbahani

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 633684615

Email address

roozbahani@arakmu.ac.ir

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

Arak

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

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

City

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

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Nasrin Roozbahani

Position

Faculty member

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Pardis Danshgae, Basij square, Arak, Iran

City

Arak

Postal code

38181-4-6851

Phone

+98 86 3368 4615

Fax

Email

roozbahani@Gmail.com; roozbahani@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Nasrin Roozbahani

Position

Ph.D of Health Education

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Pardis Danshgae, Basij square, Arak, Iran

City

Arak

Postal code

38181-4-6851

Phone

+98 86 3368 6443

Fax

Email

roozbahani@Gmail.com; roozbahani@arakmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Nasrin Roozbahani

Position

Ph.D of Health Education

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Pardis Danshgae, Basij square, Arak, Iran

City

Arak

Postal code

38181-4-6851

Phone

+98 86 3368 4615

Fax

Email

roozbahani@Gmail.com; roozbahani@arakmu.ac.ir

Web page address

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