

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparing the effect of aromatherapy Rose oil and warm water in footbath in active phase of labor, on anxiety and pain severity in primiparous women

#### Protocol summary

##### Summary

The aim of study: Comparison effect of Aromatherapy oil Rose and warm water Footbath in active phase of labor, on Anxiety and Pain severity in primiparous women. A Randomized, 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. No known history of allergy and asthma and anxiety and depression. 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: 120. Type of Intervention: inhalation, foot bath and foot bath with essential oil of Damask rose and hot water. Time involved: the active phase of labor and transitional. outcomes: reducing anxiety and labor pain.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112192751N4**

Registration date: **2012-03-19, 1390/12/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-03-19, 1390/12/29

##### Registrant information

##### Name

Masoomeh Kheirkhah

##### Name of organization / entity

Iran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8247 1000

##### Email address

kheirkhah@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2012-04-03, 1391/01/15

##### Expected recruitment end date

2012-08-21, 1391/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of aromatherapy Rose oil and warm water in footbath in active phase of labor, on anxiety and pain severity in primiparous women

##### Public title

The effect of aromatherapy on pain and anxiety of labor

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: 1- primiparous women with physical and mental health patients in the active phase; 2- the prediction of vaginal delivery with a normal history and physical examination by a medical team. 3- 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; 4- with a singleton pregnancy, cephalic view; 5- no risk of hypertension, diabetes and other medical disorders in pregnancy; 6- no history of asthma, allergies; 7- No known disease, anxiety and depression; 8- Failure to take anti-anxiety and depression as a routine; 9- No risk of skin diseases like eczema, and any wound in the foot bath; 10- Having spontaneous contractions; 11- Technology and the use of painkillers such as pethidine and anxiety during labor, entonox, acupressure, acupuncture, etc. Exclusion criteria: 1- 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; 2- Sensitivity and allergy to the use of essential oils; 3- Lack of desire to continue participating in the study; 4- Use of drugs such as oxytocin labor catalyst; 5- Use of an analgesic such as pethidine.

#### 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: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### 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

Tehran University of Medical Sciences

###### Street address

Central apartment of Tehran University of Medical Sciences, Keshavarz blvd

###### City

Tehran

###### Postal code

##### Approval date

2012-02-18, 1390/11/29

##### Ethics committee reference number

90/130/2260/3

### Health conditions studied

#### 1

##### Description of health condition studied

delivery

##### ICD-10 code

O94-O99

##### ICD-10 code description

Other obstetric conditions, not elsewhere classified

### Primary outcomes

#### 1

##### Description

Anxiety

##### Timepoint

Anxiety during pregnancy: before and immediately after intervention and anxiety before and 24 hours after the active phase of labor

##### Method of measurement

anxiety visual analog scale anAnxiety Inventory Spielberger

#### 2

##### Description

Pain

##### Timepoint

Every 30 minutes

##### Method of measurement

Visual analogue of pain

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Group 2: bathing the feet with warm water for 10 minutes.

##### Category

Other

#### 2

##### Description

Control group: routine delivery room care.

##### Category

N/A

#### 3

##### Description

Group 1: inhalation and bathing the feet with the oil of Damask rose for 10 minutes.

**Category**

Other

**Recruitment centers**

1

**Recruitment center****Name of recruitment center**

Shahid Akbarabadi Hospital

**Full name of responsible person**

Nassime Setayesh vali pour

**Street address**

Tehran

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Masood Younesian

**Street address**

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 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

School of nursing and midwifery, Tehran university of medical sciences

**Full name of responsible person**

Nassimeh Setayesh vali pour

**Position**

Senior midwifery student

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

School of Nursing and Midwifery, Tohid

**City**

Tehran

**Postal code****Phone**

+98 216822221

**Fax****Email**

setayesh\_nassim64@yahoo.com

**Web page address****Person responsible for updating data****Contact****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*