Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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/د

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
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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