Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparision of the effects of aromatherapy with roses and lavender ecxtract on pain and anxiety of active phase of labor in nulliparous women

Protocol summary

Study aim
Comparison of the effect of aromatherapy with rose extract and lavender bird extract on the anxiety of delivery active phase in nulliparous women

Design
Clinical trials with community-based control group, parallel groups, single-blind and randomized

Settings and conduct
This research was carried out at the Maternity ward of Amiralmomenin Hospital in Zabol. The pain intensity of the samples was measured 3 times in dilatation of 4-5cm, 7-8 cm and 8-10 using pain ruler. This study was carried out single blind. Blinding: Interventions in this research are carried out by a researcher and the evaluation form is completed by another person who is not aware of the type of intervention used.

Participants/Inclusion and exclusion criteria
Single pregnancy; gestational age 38-42 week; age 18-35; cephalic presentation ; dilatation of more than 3 cm; absence of asthma and allergy; non-complications during pregnancy and lactation; lack of olfactory problems; sensitivity to herbal drugs; lack of anxiety disorder Known depression; Lack of history of infertility and the onset of thyroid disease

Intervention groups
There were 3 therapeutic groups in the study: Aromatic scent with rose, lavender, distilled water. Intervention group 1: In the rose group a piece of cloth was impregnated with 0.2 ml of the rose oil and was attached to the collar of the patients and was repeated every 15 minutes. Intervention group 2: In the lavender group a piece of cloth was impregnated with 0.2 ml of lavender essential oil and was attached to the collar of the samples and was repeated every 15 minutes. Control group: 1 drop of distilled water was used and the process was repeated every 15 minutes.

Main outcome variables
Anxiety; Labor pain; Normal delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180513039632N1**
Registration date: **2018-06-09, 1397/03/19**
Registration timing: **retrospective**

Last update: **2018-06-09, 1397/03/19**
Update count: **0**

Registration date
2018-06-09, 1397/03/19

Registrant information

Name
Sanaz Nehbandani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3222 8046

Email address
snehbandani2013@zbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-22, 1396/06/31

Expected recruitment end date
2018-04-20, 1397/01/31

Actual recruitment start date
2017-09-22, 1396/06/31

Actual recruitment end date
2018-04-20, 1397/01/31

Trial completion date
empty

Scientific title
Comparision of the effects of aromatherapy with roses and lavender ecxtract on pain and anxiety of active phase of labor in nulliparous women

Public title
Studying the Effect of Aromatherapy on Pain and Anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Gestational age of 38-42 week Being at the age of 18-35 years Cervical dilatation of more than 3 CM Singleton pregnancy

Exclusion criteria:
History of asthma and allergies Known liver, gallbladder and respiratory tract disease Complications during pregnancy and maternity Olfactory problems and sensitivity to herbal medicine Anxiety and depression History of infertility and especially thyroid disease

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization. Random unit: Individual. Instrumentation: Using colored cards. How to make sequences: random

Blinding (investigator's opinion)
Single blinded

Blinding description
All interventions in this research are done by the researcher and the information registration form and the pain assessment scale are completed by another person who are not aware of the type of intervention used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zabol University of Medical Sciences

Street address
No8, Taleghani 47, Taleghani street

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861784678

Approval date
2016-12-24, 1395/10/04

Ethics committee reference number
ZBMU.REC.1395.83

Health conditions studied

1

Description of health condition studied
Labor pain

ICD-10 code
000-099

ICD-10 code description
080-084

2

Description of health condition studied
anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
labor pain

Timepoint
At the beginning of the study and at 4-5 cm, 6-7 cm and 8-10 cm dilatation

Method of measurement
McGill Pain Relief Questionnaire

2

Description
Anxiety

Timepoint
Before and after intervention

Method of measurement
Spielberger Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Rose concentration 1%, produced by Barij Essen Company. In the rose group a piece of cloth was impregnated with 0.2 ml of the rose oil and was attached to the collar of the patients and patient inhaled the rose smell. This process starts from the onset of the labor active phase and was repeated every 15 minutes.
Category
Other

2

Description
Intervention group 2: The lavender concentration produced by Barij Essen. That was prepared by distillation method with concentration of 1.5% of unopened flowers and olive oil was used as the carrier. In this group, a piece of cloth was impregnated with 0.2 ml of the rose oil and was attached to the collar of the patients and patient inhaled the rose smell. This process starts from the onset of the labor active phase and was repeated every 15 minutes.
Category
Other

3

Description
Control group: Distilled water.A drop of distilled water was stacked on a piece of cloth and was attached to the patient's collar. The process was repeated every 15 minutes.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Zabol Amiralmomenin Hospital
Full name of responsible person
Sanaz Nehbandani
Street address
Taleghani 47, Taleghani street, Zabol
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861784678
Phone
+98 54 3222 8046
Email
snehbandani2013@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zabol University of Medical Sciences
Full name of responsible person
خدیجه رضایی کیخایی
Street address
Zabol Nursing and Midwifery Faculty, Ferdowsi 3, Ferdowsi street
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861734184
Phone
+98 54 3223 0765
Email
snehbandani2013@zbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zabol 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
Zabol University of Medical Sciences
Full name of responsible person
Sanaz Nehbandani
Position
Consultant
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No 8,Taleghani 47, Taleghani street
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861784678

Phone
+98 54 3222 8046
Fax
Email
snehbandani2013@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zabol University of Medical Sciences
Full name of responsible person
Sanaz Nehbandani
Position
Consultant
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No 8,Taleghani 47, Taleghani street
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861784678
Phone
+98 54 3222 8046
Fax
Email
snehbandani2013@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zabol University of Medical Sciences
Full name of responsible person
Sanaz Nehbandani
Position
Consultant
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No 8,Taleghani 47, Taleghani street
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861784678
Phone
+98 54 3222 8046
Fax
Email
snehbandani2013@gmail.com

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
Not applicable
Title and more details about the data/document
The main consequences will be published in the article
When the data will become available and for how long
2018
To whom data/document is available
Researchers working in academia
Under which criteria data/document could be used
For scientific research
From where data/document is obtainable
Sanaz Nehbandani. snehbandani2013@zbmu.ac.ir
What processes are involved for a request to access data/document
After getting permission from relevant individuals, there is the possibility of sending data
Comments