Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Rosa Damascena effect on pain and anxiety in first stage of labor in nulliparous women

Protocol summary

Summary

Aims: The overall purpose: the rosa damascena effect on pain and anxiety in first stage of labor in nulliparous women. specific objectives: 1. The pain of the first stage of labor in nulliparous women in both groups aromatherapy whit rosa damascena and the control group (normal saline). 2. to comper of pain in First stage of labor in nulliparous women in the two groups (Rose oil) and control (normal saline) 3. The anxiety of the first stage of labor in nulliparous women in both groups aromatherapy whit rosa damascena and the control group (normal saline). 4. to comper of anxiety in First stage of labor in nulliparous women in the two groups (Rose oil) and control (normal saline) Before starting work on demographic and obstetric, STAI anxiety questionnaire to be completed by the subjects described the pain is and how to use a ruler. Beginning of the active phase dilatation 4 cm aromatherapy with essential oils of Rose starts and continues until delivery. In this study, both times in aromatherapy 08/0 ml 2 drops of rose essential oil is applied to the gas sample is connected to clothes. In the control group 08/0 ml saline soaked gauze dress samples to be connected. This is repeated every half hour in both groups. 3 times the pain involved in dilatation of 5-4 cm, 7-6 cm and 10-8 cm, ten minutes after the inhalation of essential oils rose at the end of each contraction is measured, then compared the two groups intervention research results will be achieved. Instruments used in this study included demographic characteristic and obstetric instruments, observation and examination Czech lists, numeric pain rating scale and the Spilberger anxiety questionnaire.

General information

Acronym

Rosa Damascena

IRCT registration information

IRCT registration number: **IRCT201306258801N3**

Registration date: **2013-07-28, 1392/05/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-28, 1392/05/06

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University for Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Rosa Damascena effect on pain and anxiety in first stage of labor in nulliparous women

Public title

Rosa Damascena effect on pain and anxiety in first stage of labor in nulliparous women

Purpose
Supportive

Inclusion/Exclusion criteria
Characteristics of the subjects (inclusion criteria): The Iranian women, primigravida, who are aged between 18 and 35 years, with term pregnancy; singleton fetuses with vertex views are being studied. The onset of spontaneous contraction and dilation of the examination on arrival, 4-3 cm, at the right hip; the mother of 8 hours is not taking analgesic medications; have no pregnancy complications such as preeclampsia, gestational diabetes and obstetric complications such as decolman, previa abnormal fetal heart rate at baseline are known gastrointestinal disease, respiratory ... according to their own records and do not have an allergy to herbal and have no problem with the smell. Exclusion criteria: completion of previous emergency caesarean; withdrew from the partnership before the completion of the study.

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
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
shaied Beheshti University of Medical Sciences, Tehran

Street address
School of Nursing and Midwifery Niayesh Croos Vali Asr Tehran

City
Tehran

Postal code

Approval date
2013-06-15, 1392/03/25

Ethics committee reference number
1392-1-86-11354

2

Ethics committee

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Postal code

Approval date
2013-06-15, 1392/03/25

Ethics committee reference number
1392-1-86-11354

Health conditions studied

1

Description of health condition studied
Pain and anxiety in first stage of labor

ICD-10 code
O60-75

ICD-10 code description
Complications of labour and delivery

Primary outcomes

1

Description
Labor pain in active phase

Timepoint
Before intervention, three times after intervention in dilataions 4 to 5 cm, 6 cm to 7, 8 to 10 cm

Method of measurement
Numeric pain rating scale (ten-centimeter ruler Pain)

2

Description
Anxiety in first stage of labor

Timepoint
Before intervention, twice after intervention in dilatasions of 4 to 5 cm, 8 to 10 cm

Method of measurement
STAI anxiety questionnaire

Secondary outcomes

1

Description
Nausea

Timepoint
After intervention hourly untill the end of intervention

Method of measurement

View with questions

Intervention groups

1

Description
Intervention group: Essence of Rosa damascena inhaled in the active phase of labor, ie the dilatation of 4 cm to 10 cm for women nulliparous be the case that every half-hour, two drops of oil equivalent 0/08 cc of the gas thread is poured heavily pain and anxiety after the intervention of certain dilation is measured.
Category
Placebo

2

Description
The control group received placebo or placebo (normal saline) instead of oil used. Occurs because of the active phase of labor, ie the dilatation of 4 cm to 10 cm for women nulliparous be the case that every half-hour, two drops of normal saline, which is equivalent to 0/08 cotton cc gas is poured on pain and anxiety after the intervention of certain dilation is measured
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Javadol Aemmeh hospital, Jajarm city
Full name of responsible person
Street address
City
Jajarm

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shaied Beheshti University of Medical Sciences
Full name of responsible person
Mr Dr mahammad rahmati rodsari
Street address
Research- Shaied Beheshti University of Medical Sciences – Taleghani St. - Tabnak St.- Evin Chamran Highway -Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
shaied Beheshti 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

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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