

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

Name

Masoumeh Simbar

Name of organization / entity

Shahid Beheshti University for Medical Sciences

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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

Name of ethics committee

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Postal code

Approval date

2013-06-15, 1392/03/25

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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 dilatations 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

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

shaid 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

shaid 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

Contact

Name of organization / entity

Shaied Beheshti University of Medical Sciences

Full name of responsible person

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Position

Faculty member

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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