

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Study of Effect of Citrus aurantium Aroma on Severity of Labor Pain and Anxiety in Patients Admitted to Vali-e Asr Hospital, Touyserkan County in 2013

Protocol summary

Summary

The aim of the study is to evaluate the effect of Citrus aurantium Aroma on severity of labor pain and anxiety in patients admitted to Vali-e Asr Hospital, Touyserkan County, Iran in 2013. Inclusion Criteria: be Iranian; be nulliparous; be at the age of 18-35 years old; have a singleton term pregnancy; fetal presentation should be vertex; onset of contractions should be spontaneous, and at the beginning of admission, have a 3 to 4-cm dilatation; appropriate pelvic position; estimated fetal weight should range from 2500 to 4000 gr; amniotic sac should be sound when admitting to the study; over the past 8 hours, mother have not used analgesic medicines; have no known liver, gallbladder, and respiratory disease records in her file; according to the file, have no complication during pregnancy such as pre-eclampsia, bleeding and infection; according to her, have not olfactory problems; according to her, not sensitive to herbal medicines. Exclusion criteria: emergency cesarean before completing the study; sensitive to citrus scents and non-tolerance during the study term; obstetric complications such as vaginal bleeding during the study; analgesic intake during the study. The minimum sample needed in each of aromatherapy and placebo groups is 63 persons. In aromatherapy group, 4 ml of citrus aurantium is used. Aromatherapy begins from dilatation of 3-4 cm, and severity of labor pain is measured 20 min after aromatherapy, after which aromatherapy continues until delivery time. In aromatherapy group, 4 ml of citrus scents is stained with gas and attached to the collar of the patients. Every half hour, the prescription will be repeated. In control group, 4 ml of normal saline is stained with gas, and every half hour, this is repeated. Severity of labor pain and anxiety before and after intervention in 3-4, 5-7, and 8-10 dilatations is measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301306807N6**

Registration date: **2013-07-17, 1392/04/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-17, 1392/04/26

Registrant information

Name

Sedigheh Amir Ali Akbari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2272 9240

Email address

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research Dept, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-04-22, 1392/02/02

Expected recruitment end date

2014-01-22, 1392/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Study of Effect of Citrus aurantium Aroma on Severity of Labor Pain and Anxiety in Patients Admitted to Vali-e Asr Hospital, Touyserkan County in 2013

Public title
Study of Effect of Citrus aurantium Aroma on Severity of Labor Pain and Anxiety

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: be Iranian; be nulliparous; be at the age of 18-35 years old; have a singleton term pregnancy; fetal presentation should be vertex; onset of contractions should be spontaneous, and at the beginning of admission, have a 3 to 4-cm dilatation; appropriate pelvic position; estimated fetal weight should range from 2500 to 4000 gr; amniotic sac should be sound when admitting to the study; over the past 8 hours, mother have not used analgesic medicines; have no known liver, gallbladder, and respiratory disease records in her file; according the file, have no complication during pregnancy such as pre-eclampsia, bleeding and infection; according to her, have not olfactory problems; according to her, not sensitive to herbal medicines. Exclusion criteria: emergency cesarean before completing the study; sensitive to citrus scents and non-tolerance during the study term; obstetric complications such as vaginal bleeding during the study; analgesic intake during the study.

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

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **126**

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

Shahid Beheshti University of Medical Sciences and health services

Street address

Shahid Beheshti University of Medical Sciences, Velenjak Street, Shahid Chamran High Way, Tehran, Iran

City

Tehran

Postal code

1985717443

Approval date

2013-04-21, 1392/02/01

Ethics committee reference number

400/634

Health conditions studied

1

Description of health condition studied

childbirth pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

2

Description of health condition studied

anxiety of childbirth

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

intensity of pain

Timepoint

before and after intervention in 3-4, 5-7, and 8-10 dilatations

Method of measurement

Numeric Rating scale Ruler

2

Description

anxiety

Timepoint

before and after intervention in 3-4, 5-7, and 8-10 dilatations

Method of measurement

Speilberger checklist

Secondary outcomes

empty

Intervention groups

1

Description

In aromatherapy group, 4 ml of citrus scents is stained with gas and attached to the collar of the patients. Every half hour, the prescription will be repeated.

Category

Treatment - Drugs

2

Description

In control group, 4 ml of normal saline is stained with gas, and every half hour, this is repeated.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital in Tuysarkan city

Full name of responsible person

Street address

City

Tuysarkan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research Dept of School of Nursing and Midwifery Shahid Beheshti University of M

Full name of responsible person

Dr Masoumeh Simbar

Street address

School of Nursing and Midwifery, Opp. Shahid Rajaei Heart Hospital, Niyayesh Crossing, Vali-e Asr Ave., Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor for Research Dept of School of Nursing and Midwifery Shahid Beheshti University of M

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

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Namazi

Position

Master student of midwifery

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery; Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seddighe Amir Ali Akbari

Position

MSc

Other areas of specialty/work

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School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Opp. Shahid Rajaei Heart Hospital, Niyayesh Crossing, Vali-e Asr Ave., Tehran

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Web page address	<i>empty</i>
Person responsible for updating data	Statistical Analysis Plan <i>empty</i>
Contact	Informed Consent Form <i>empty</i>
Sharing plan	Clinical Study Report <i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Analytic Code <i>empty</i>
Study Protocol	Data Dictionary <i>empty</i>