Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Assessment of the effect of matrica chamomillabreath on anxiety and pain of delivery on primigravida women who referred to Abhar Emdadi hospitals delivery room in 2013.

Protocol summary

Summary

The aim of this study is to investigate the effect of matrica chamomilla aroma on anxiety and pain of delivery on primigravida women who referred to Abhar Emdadi hospitals delivery room in 2013. This is a randomized, single blind, placebo controlled, single centered phase II trial. Study population: Iranian primigravida women aged between 18 and 35, gestational age of 37-42 weeks who didn't mention any auditory , olfactory and neuro-psychic disorders; hadn't taken any narcotics eight hours before any active phases in delivery process; hadn't had any uterine surgery , placenta previa , history of cerclage and any indication for caesarian section. Exclusion criteria: The existence of any disorder in fetal heart rate , placenta abruptia , severe preeclampsia and any problem during labor, and being allergic to matrica chamomilla. Sample size is 126 women. In the intervention group two drops of chamomile were used on a guaze and was kept at a distance of 5 to 10 cm from the subject's nose for one minute. In the control group two drops of distilled water were used in the same manner. Aroma therapy was repeated three times in half an hour intervals at 3-4, 5-7 and 8-10cm dilatations. Pain was measured using McGill pain scale before intervention and three times after aroma therapy at each dilatation. Anxiety was measured using spilberger questionnaire at the same intervals as pain's.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308066807N7**
Registration date: **2014-12-20, 1393/09/29**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-12-20, 1393/09/29

Registrant information

Name

Sedigheh Amir Ali Akbari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chanceller for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

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

Assessment of the effect of matrica chamomillabreath on anxiety and pain of delivery on primigravida women who referred to Abhar Emdadi hospitals delivery room in 2013.

Public title
Assessment of the effect of chamomile breath on anxiety and pain during delivery in primigravida women
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria: Iranian primagravida women aged between 18 and 35 with gestation age of 37-42 weeks who had live single fetus without any major anomaly and with cephalic presentation and having normal weight of 2500-3400 grams. Mother should have a normal Body Mass Index at the time of entry and shouldn't have any auditory, olfactory and mental problems; not suffered from any special medical disorders, should not have any known acute and chronic nouro- psychic illnesses ; not taking any special neuro – psychic medicine; not having any acute and chronic pain like migraine; not taking any narcotics eight hours before any active phases in delivery process; not having any indication of caesarian like uterine surgeries , placenta previa, cephalopelvic disproportion , preeclampsia , any history of cerclage and fetus distress , any history of alcohol and narcotic addiction. Exclusion criteria: observing any kind of allergy or intolerance to chamomile; any disorders in labor process which led to bleeding; hypertension; disorders in fetus heart rate; prolapse of cord; placenta abruptia; prolonged rupture of membrane and inspecting meconium or making a decision to do delivery using instruments or surgery
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **126**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
According to sampling days , the candidates were categorized to two intervention and control group using pockets A and B.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences,Velenjak,Tehran
City
Tehran
Postal code
-
Approval date
2013-09-08, 1392/06/17
Ethics committee reference number
400/4013

Health conditions studied

1

Description of health condition studied
Pain and anxiety during normal delivery
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Pain
Timepoint
Pain was measured using McGill pain scale before intervention and three times after aroma therapy at each dilatation interval at 3-4, 5-7 and 8-10cm.
Method of measurement
McGill Pain Questionnaire

2

Description
Anxiety
Timepoint
Anxiety was measured using spilberger questionnaire before intervention and three times after aroma therapy at each dilatation interval at 3-4, 5-7 and 8-10cm.
Method of measurement
spilberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group two drops of chamomile were used on a guaze and was kept at a distance of 5 to 10 cm from the subject’s nose for one minute.

Category

Treatment - Other

2

Description

In the control group two drops of distilled water were used on a guaze and was kept at a distance of 5 to 10 cm from the subject’s nose for one minute.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emdadi Abhar Hospital

Full name of responsible person

Abolhasan Rafiee

Street address

Emdadi Abhar Hospital, Khoramshahr Street, Abhar

City

Abhar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahid Beheshti University of Medical Sciencs

Full name of responsible person

Doctor Masoume Simbar

Street address

Obstetrics department, Valiasr Street, 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 of Shahid Beheshti University of Medical Sciencs

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, Midwifery Shahid Beheshti

Full name of responsible person

Solmaz Heydari Fard

Position

Master of Midwifery

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Person responsible for scientific inquiries

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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