Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Chammomil fragrance impact on anxiety and pain after cesarean section in nulliparous women

Protocol summary

Summary

The aim of this study was to investigate the effect of chamomile on the severity of postoperative pain and post-cesarean anxiety in primipara mothers. Design: Double blind clinical trial with placebo method: In this study, after obtaining informed consent, patients will be randomly divided into two groups of intervention and control. 43 people will be in every group. Members of both groups at the first completed the questionnaire of visual acuity and Spilberger's apparent and hidden anxiety. Then the members of the intervention group inhale the chamomile fragrance for ten minutes, and the members of the control group inhale the distilled water. After 10 minutes of inhalation, again, in both groups, the intervention and control, the visual acuity questionnaire and Spilberger's apparent and hidden anxiety are completed. Inclusion criteria: age 18 to 35 years؛ use of spinal anesthesia؛ transverse incision؛ duration of operation less than 90 minutes؛ Iranian race؛ singleton pregnancy؛ absence of simultaneous surgery؛ Not having chamomile sensitivity؛ lack of anxiety disorders. exclusion criteria: Inertia during or after surgery؛ Ileus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052834169N1**
Registration date: **2017-09-05, 1396/06/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-05, 1396/06/14

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Gonabad University Of Medical Sciences

Expected recruitment start date

2017-06-01, 1396/03/11

Expected recruitment end date

2017-07-31, 1396/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Chammomil fragrance impact on anxiety and pain after cesarean section in nulliparous women

Public title

Chammomil effect on pain and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria، 18 to35 years، the use spinal anesthesia، transects، opeation times less than 90 minutes، iranian race؛single pregnancy، no time surgery، insensivity to MC، the absence of anxiety disorders؛ exclusion criteria: ileus، inersi during or after operation.

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: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Gonabad University Of Medical Sciences
Street address
Gonabad University Of Medical Sciences
City
Gonabad
Postal code
Approval date
2017-02-19, 1395/12/01
Ethics committee reference number
IR.GMU.REC.1395.124

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
f41.1
ICD-10 code description
Generalized anxiety disorder

2

Description of health condition studied
Pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
PAIN
Timepoint
10 MINUTES
Method of measurement
VAS

2

Description
anxiety
Timepoint
10minute
Method of measurement
spilberg anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Seven drops of chamomile fragrance for 10 minutes inhalation
Category
Treatment - Drugs

2

Description
control group: Seven drops of strill water for 10 minutes .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Hospital، Neishaboor
Full name of responsible person
Dr Noori
Street address
Neishabour، Hakim Hospital
City
Neishabour

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University Of Medical Sciences

Full name of responsible person
Dr Alireza MohammadZadei
Street address
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City
Gonabad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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