Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of aromatherapy with rose oil (Rosa damascena Mill.) inhalation on primary dysmenorrhea: A prospective randomized controlled clinical trial

Protocol summary

Study aim

The primary purpose of our research evaluates hypothesis " the rose oil aromatherapy which added to the standard treatment of primary dysmenorrhea decrease pain scores more than Control Group".

Design

Prospective, parallel group, randomized controlled clinical trial. Forty-three patients in each group and 86 patients in total will be included in the study. The random number generation program of the Microsoft Office Excel program will be used to make randomization sequence.

Settings and conduct

The volunteers will be diveded two group, according to the randomization, as Group Rose (Group R) and Group Control (Group C). All patients in Group C and Group R will use standard analgesics drug (diclofenac sodium 50 mg enteric film tablet) for abdominal pain in the menstrual period. In group R, in addition to standard analgesics drug, rose oil will be given to the volunteers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients who have primary dysmenorrhea, and a painful menstrual period complaint; The patients who are in the ASA I risk group; being in the age range of 18-24 years. Exclusion criteria: The patients who have abnormal menstrual bleeding; allergy to rose oil and analgesic drugs; the history of asthma-like respiratory disease.

Intervention groups

The Rose oil was obtained by distillation method from in Ahi Evran University Faculty of Agriculture in the region of the Kırşehir, Turkey. (Citronellol (%26,14), Nonadecane (%21,32), etc). The dark bottle, containing 2-3 drop rose oil, and odorless tissue paper which has the same trademark and specification will be given to the volunteers. Firstly, the patients, VAS score >4, will use a standard analgesic drug. And then they will evacuate the rose oil in the bottle onto the tissue paper. They will cover on their faces with this tissue and they will sniff him for 15 minutes.

Main outcome variables

The VAS (Visual analog scale) pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180324039145N2**
Registration date: **2018-09-25, 1397/07/03**
Registration timing: **prospective**

Last update: **2018-09-25, 1397/07/03**
Update count: **0**

Registration date

2018-09-25, 1397/07/03

Registrant information

Name

Recai Dagli

Name of organization / entity

Ahi Evran University Faculty of Medicine

Country

Turkey

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-01, 1397/07/09

Expected recruitment end date

2019-10-01, 1398/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of aromatherapy with rose oil (Rosa damascena Mill.) inhalation on primary dysmenorrhea: A prospective randomized controlled clinical trial

Public title

Rose oil aromatherapy treatments for diysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients diagnosed the primary dysmenorrhea have a painful menstrual period complaint in the ASA (American Society of Anesthesiologists) I risk group in the age range of 18-24 years old

Exclusion criteria:

The patients who are constantly using analgesics for other reasons The patients who are treated for any upper respiratory tract disease that may cause edema in the nasal mucosa and may prevent smelling The patients who have anosmia diagnosed by otorhinolaryngologists The patients who have abnormal menstrual bleeding The patients who have allergies to rose oil and analgesic drugs, the asthma-like respiratory disease

Age

From **18 years** old to **24 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The random number generation program of the Microsoft Office Excel program will be used to make randomization sequence. The cards named Group Rose (Group R) and Group Control (Group K) will be used to conceal the randomization sequence. The method of concealment will be closed envelopes. 86 blocks will be used for randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Clinical Investigations Ethics Committee, the Ahi Evran University

Street address

No.100, Bagbasi St., Kirsehir, Turkey

City

Kirsehir

Postal code

40100

Approval date

2018-05-22, 1397/03/01

Ethics committee reference number

2018-10/95

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

Visuel analog scale (VAS) pain scores

Timepoint

Before and after administration in the menstrual period for each patient.

Method of measurement

Visuel analog scale (VAS) (between 1-10 score)

Secondary outcomes

1

Description

analgesic consumption of the patients for twenty-four hours

Timepoint

First twenty-four hours.

Method of measurement

Asking from patients

Intervention groups

1

Description
Intervention group 1 (Group Rose or Group R): The Rose oil will be produced through distillation method at Ahi Evran University Faculty of Agriculture in the region of the Kırşehir, Turkey. The rose oil product used in this study is not licensed in the country. Rose oil product used in this study contains Citronellol (%26,14), Nonadecane (%21,32), Heneicosane (%10,33), Geraniol (%5,08), Methyl Eugenol (%1,46), Ethanol (%0,48), Linalool (%0,12). The dark bottle, containing 2-3 drop rose oil, and odorless tissue paper which has the same trademark and specification will be given to the volunteers. Firstly, the patients will use a standard analgesic drug (diclofenac sodium 50 mg enteric film tablet, max three times a day) (Voltaren, Novartis). And then they will evacuate the rose oil in the bottle onto the tissue paper. They will cover on their faces with this tissue and they will sniff it for 15 minutes (one time).

Category
Treatment - Drugs

2

Description
Intervention group 2 (Group C): The patients with VAS score >4 will use only a standard analgesic drug (diclofenac sodium 50 mg enteric film tablet, maximum three times a day)(Voltaren, Novartis)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Obstetrics and Gynecology, Faculty of Medicine, Ahi Evran University

Full name of responsible person
Selda Songur Dagli

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Title of funding source
Department of Obstetrics and Gynecology, Faculty of Medicine, Ahi Evran University

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Faculty of Medicine, Ahi Evran University

Full name of responsible person
Recai Dagli

Position
Ass.Prof.Dr.

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available