

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study effect of Aromatherapy with Rose extract in controlling postoperative pain in inguinal hernia operation

Protocol summary

Summary

Objectives: To investigate the effect of Rose extract on pain control after inguinal hernia surgery in Hamedan Shahid Beheshti Hospital. **Design:** A randomized, double blind clinical trial that the main author and patients are unaware of drugs groups. The sample size in this study was 80 people who were assigned to control and intervention groups with 40 member in each group. **Setting and conduct:** Patients undergoing inguinal hernia surgery who will be referred to Shahid Beheshti Hospital in Hamadan in 1396 and 1397 years. **Inclusion criteria:** Age 20 to 50 years; ASA; Classes 1 and 2; No history of opium and psychotropic drugs; No Long-term used anti inflammatory non-opoid; No systemic disease; Not sensitive to used drugs; Woman is not pregnant. **Exclusion criteria:** lack of access to the patient for measuring pain; patient's inability to determine the pain score for any reason; Morbidity sensitivity to the Rose extraction in the intervention group. **Intervention:** In the intervention group, 4 drops of rose extract of 4% were made by Barij Essence, 15 minutes prior to the end of inguinal hernia operation, and through the nares(2 drops in each nostril). Patients were randomly assigned into two groups with 40 members and assigned to General Anesthesia and same Protocols. The primary outcome of this study was to investigate the score of the post operative pain and the secondary outcome including the complications of the used drugs, the hemodynamic status, and the amount of analgesics consumed by the patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703139597N3**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Seyed Mohamad Zolhavarieh

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0020

Email address

sm.zolhavarieh@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-11-16, 1396/08/25

Expected recruitment end date

2018-05-15, 1397/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study effect of Aromatherapy with Rose extract in controlling postoperative pain in inguinal hernia operation

Public title

Effect of Aromatherapy with Rose extract in controlling postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) Age of 20-50 years; (b) Patients with class 1 or 2 according to the American Society of Anesthesiology scoring criteria; (c) No history of opium and psychotropic drugs; (d) No Long-term used anti-inflammatory non-opioid; (e) No systemic disease; (f) Not sensitive to used drugs; (g) Woman is not pregnant.

Exclusion criteria: (a) Lack of access to the patient for measuring pain; (b) the patient's inability to determine the pain score for any reason; (c) Morbidity sensitivity to the Rose extraction in the intervention group.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Using random block in two intervention and control groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

ice-chancellor of Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

IR.UMSHA.REC.1396.418

Health conditions studied

1

Description of health condition studied

Pain localized to other parts of lower abdomen

ICD-10 code

R10.3

ICD-10 code description

Pain localized to other parts of lower abdomen

2

Description of health condition studied

Inguinal hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Pain score

Timepoint

1, 6, 12, , and 24 hours after surgery

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

side effects of drugs

Timepoint

1, 6, 12 and 24 hours after surgery

Method of measurement

questionnaire

2

Description

Hemodynamic status

Timepoint

1, 6, 12 and 24 hours after surgery

Method of measurement

Esphigmomanometry and pulse oximetry

3

Description

Analgesic dosage used

Timepoint

1, 6, 12 and 24 hours after surgery

Method of measurement

questionnaire

Intervention groups

1

Description

In the intervention group, 4 drops of rose extract of 4% were made by Barij Essence, 15 minutes prior to the end of inguinal hernia operation, and through the nares (2 drops in each nostril).

Category

Treatment - Other

2

Description

In the control group, 4 drops of distilled water, 15 minutes prior to the end of inguinal hernia operation, and through the nares (2 drops in each nostril).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Seyed Mohammad Zolhavarieh

Street address

Shahid Beheshti Hospital, Eram Blv.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Vice-chancellor of Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor of Research and Technology, Hamadan
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

Hamadan University of Medical Sciences

Full name of responsible person

Seyed Mohammad Zolhavarieh

Position

Board of Anesthesiology

Other areas of specialty/work

Street address

Shahid Beheshti Hospital Eram Blv.

City

Hamadan

Postal code

Phone

+98 81 3838 0749

Fax

Email

dsmbzsolhavarieh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Seyed Mohammad Zolhavarieh

Position

Board of Anesthesiology

Other areas of specialty/work

Street address

Shahid Beheshti Hospital Eram Blv.

City

Hamadan

Postal code

Phone

+98 81 3838 0749

Fax

Email

dsmbzsolhavarieh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Seyed Mohammad Zolhavarieh

Position

Board of Anesthesiology
Other areas of specialty/work
Street address
Hamadan
City
Hamadan
Postal code
Phone
+98 81 3838 0749
Fax
Email
dsmbsozhavarieh@gmail.com
Web page address

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