

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of lavender essence on patient s anxiety due to tooth extraction ,randomized controlled trial

Protocol summary

Study aim

assessment effectiveness of lavender essence on anxiety due to tooth extraction

Design

In this control randomized clinical trial single blinded with parallel group 60 patients come to Kermanshah dental college who have inclusion criteria assign to the groups.

Settings and conduct

60 patients who come to Kermanshah dental college for tooth extraction allocate 2 groups with randomized number chart. give to patients anxiety questionnaire test to complete then if allocate even number to patient give lavender to smell and patients with odd number give almond oil to smell .patients smell odors on gauze for 20 minutes and then complete that questionnaire again.

Participants/Inclusion and exclusion criteria

inclusion criteria:1-patients between 18-65 years 2-who candidate for extraction anterior or posterior tooth
extrusion criteria:1- impact tooth 8 surgery 2-pregnancy 3- routine smoking (minimum 1 Cigarette per day) 4-use special drugs such as sedatives (past 24 hours)5-any history of cardiac disease 6-uncontrolled hypertension(over 180 mm hg) 7-Sinusitis and Rhinitis and any thing effect on olfactory system

Intervention groups

1- control :almond oil 2- intervention: Lavender essence

Main outcome variables

Amount of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190920044824N1**

Registration date: **2019-12-19, 1398/09/28**

Registration timing: **retrospective**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

Fatemeh Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3729 2072

Email address

fatemeh.rezaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-13, 1398/06/22

Expected recruitment end date

2019-11-20, 1398/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of lavender essence on patient s anxiety due to tooth extraction ,randomized controlled trial

Public title

Determine effect of lavender's essence on patients anxiety due to tooth extraction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient between 18-65 years patient who candidate for extraction one anterior or posterior tooth

Exclusion criteria:

impact 8tooth surgery pregnancy routine smoking (minimum one cigarette per day) use sedative drugs during past 24 hours any exist history of particular systemic disease like uncontrolled hyper tension (over 180 mm hg) ,history of any cardiac disease ,sinusitis ,rhinitis ,any thing effects on olfactory system

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Use Excel soft ware for produce three digit random numbers. based on the last digit on the right patient's assign to the groups.if the last digit on the right be 1-4 give blue tube to the patient and if the last digit on the right be 5-8 give red tube to the patient and will be ignored if be 0 or 9 and produce another new number for the patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

Groups assignment phydisian and outcome assessment physician who evaluate anxiety after intervention dont aware of groups allocation ,just pharmacologist be aware of tube's content and patients cant be blind beacause of lavender 's odour.

Placebo

Used

Assignment

Parallel

Other design features

placebo is almond oil.each group smell the odour 20 minutes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of kermanshah university of medical sciences

Street address

Ethics committee,department of research and technology central building ,shahid beheshti blvd

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-10-13, 1398/07/21

Ethics committee reference number

IR.KUMS.REC.1398.693

Health conditions studied

1

Description of health condition studied

patient s anxiety due to tooth extraction

ICD-10 code

F41.9

ICD-10 code description

Anxiety

Primary outcomes

1

Description

patient anxiety due to tooth extraction

Timepoint

before and after smell odors

Method of measurement

Beck anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group 2 drop pure lavender essence which made by pharmacologist on gauze give to patients and they smell for 20 minutes and then complete Beck anxiety questionnaire again .

Category

Treatment - Other

2

Description

Control group: in this group 2 drop almond oil on gauze (with no color and smell)give to patients and they smell for 20 minutes and then complete Beck anxiety questionnaire .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Dental University

Full name of responsible person

Fatemeh Rezaei

Street address

shariati st.

City

kermanshah

Province

Kermanshah

Postal code

67139546581

Phone

+98 83 3727 7030

Email

fatemeh.rezaei@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Vice chancellor for research and technology
,kermanshah university of medical sciences,shahid
beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3729 6591

Email

Faridnajafi@kums .ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Kermanshah University Of Medical Sciences

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**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Baharsadat Ghasemiyan

Position

Under graduated student of Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

The school of Dentistry, shariati st.

City

Kermanshah

Province

Kermanshah

Postal code

67139546581

Phone

+98 83 3727 7030

Email

WWW.bahar2017ghasemiyan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fatemeh Rezaei

Position

Assistant Professor of Oral Disease Department

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Department of Oral Disease ,The School of Dentistry
,kermanshah university of medical sciences,shariati st.

City

Kermanshah

Province

Kermanshah

Postal code

67139546581

Phone

+98 83 3729 6910

Email

fatemeh.rezaei@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Bahar Sadat Ghasemiyan

Position

Under Graduated student of Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

The School of Dentistry ,Kermanshah University of
Medical sciences,Shariati st.

City

Kermanshah

Province

Kermanshah

Postal code

67139546581

Phone

+98 83 3727 7030

Email

www.bahar2017ghasemiyan@gmail.com

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