

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Citrus aurantium extract and Diazepam on preoperative anxiety and blood glucose in patients candidate for ophthalmic surgery

Protocol summary

Study aim

Determination of the effect of Citrus aurantium extract and oral Diazepam on Preoperative Anxiety and Blood Glucose in Patients Candidate for ophthalmic Surgery

Design

The present study is a clinical trial study with a control group with randomized single-blind parallel groups. Sample size: In each group 35 person. Methods: Randomize allocation is divided into three groups of 35 using block randomization.

Settings and conduct

Location: Bou Ali Sina hospital in Sari. Method: Vital signs, blood glucose level and anxiety of patients will be assessed in three phases: 1) 8 pm. 2) 10 pm. (both in the ophthalmic surgery ward) 3) next morning 8 am. before surgery (in the operating room). Relevant drug interventions will be performed by the nurse after the first phase and the researcher going to leave the room during interventions for blinding.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patient satisfaction to participate in the study
Exclusion criteria: Patient's allergy to Citrus aurantium

Intervention groups

Group one: 100 cc of Citrus aurantium extract the night before surgery
Group two: Diazepam 5 mg tablets dissolved in 100 ml of water the night before surgery
Group three: The placebo group 100 cc distilled water the night before surgery

Main outcome variables

Anxiety; Blood sugar; vital signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191005044989N1**

Registration date: **2019-11-28, 1398/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-28, 1398/09/07**

Update count: **0**

Registration date

2019-11-28, 1398/09/07

Registrant information

Name

Meysam Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3377 5816

Email address

meysam10heidari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-11-29, 1398/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Citrus aurantium extract and Diazepam on preoperative anxiety and blood glucose in patients candidate for ophthalmic surgery

Public title

The effect of Citrus aurantium extract and Diazepam on preoperative anxiety and blood glucose of ophthalmic surgery patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients satisfaction to participate in the study All patients undergoing ophthalmic surgery requiring hospitalization the night before surgery Age between 18 and 80 years No history of diseases such as hypertension and hyperthyroidism Allergic to Citrus aurantium No diabetes history

Exclusion criteria:

Patients dissatisfaction to participate in the study history of diseases such as hypertension and hyperthyroidism Any underlying diseases affecting blood sugar and anxiety of patients such as diabetes pregnant women

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate groups through randomized allocation, patients were divided into 3 groups. Each group included 35 individuals. Then to equalize groups by using Block balanced randomization and the letters A and B, patients were divided into groups. And for the Allocation concealment, the sequentially numbered, sealed, opaque envelopes was used.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher who collects data leaves the room during intervention (allocation and use of medication by patient) and is completely unaware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Research assistance, building number 2 of Mazandaran University of Medical Sciences, Moalem square, Sari

City

Sari

Province

Mazandaran

Postal code

۶۱۴۹۷۶۳۹۷

Approval date

2019-09-25, 1398/07/03

Ethics committee reference number

IR.MAZUMS.REC.1398.903

Health conditions studied

1

Description of health condition studied

Diseases associated with ophthalmic surgery like Cataract

ICD-10 code

H25.9

ICD-10 code description

Unspecified age-related cataract

2

Description of health condition studied

Diseases associated with ophthalmic surgery like Strabismus

ICD-10 code

H50.9

ICD-10 code description

Unspecified strabismus

Primary outcomes

1

Description

Anxiety score

Timepoint

Before the intervention, two hours after the intervention, and one day after the intervention.

Method of measurement

To evaluate patient's anxiety we will use Spielberger State_ Trait Anxiety Inventory questionnaire.

2

Description

The percentage of people with blood sugar above 90 mg / dL

Timepoint

Before the intervention, two hours after the intervention, and one day after the intervention

Method of measurement

To measure blood glucose level, the patient's blood sample is sent to the hospital laboratory

Email
Meysam10heidari@gmail.com

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Receiving 100 cc Citrus aurantium extract the night before surgery. In this study Citrus aurantium extract belong to Ghadah Kashan Company that has revenue operation license from agriculture association 3/1674, revenue operation license from ministry of health 12045 and sanitary making license 40/10882

Category

Treatment - Drugs

2

Description

Second intervention group: Diazepam 5 milligram pill dissolved in 100 ml of water the night before surgery. Diazepam pill produced by Loghman Health Pharmaceutical Company with Drug Registration Number 1228034190.

Category

Treatment - Drugs

3

Description

Placebo group receiving 100 cc distilled water the night before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bou Ali Sina medical center hospital, Sari, Mazandaran, Iran

Full name of responsible person

Hooshang Akbari

Street address

Bou Ali Sina hospital, Bou Ali Sina medical center, Pasdaran Blvd, Sari

City

Sari

Province

Mazandaran

Postal code

۶۱۴۹۷۶۳۹۷

Phone

+98 11 3223 3010

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

No. 140 , Amir Mazandarani Ave., Keshavarzi Blvd

City

Sari

Province

Mazandaran

Postal code

6144976397

Phone

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Email

majsaeedi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Nasiri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No. 140 , Amir Mazandarani Ave., Keshavarzi Blvd

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Hooshang Akbari
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Associate professor
Latest degree
Specialist
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Person responsible for updating data

Contact

Name of organization / entity
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Latest degree
Bachelor
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Khouzestan
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meysam10heidari@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data after unrecognizable people are Shareable

When the data will become available and for how long

Start of access period 8 month after publishing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Requirements for submitting a request: 1) The applicant must be affiliated with a scientific, research or academic institution. 2) The need to specify all the purposes for accessing the data.

From where data/document is obtainable

Responsive people: 1) Hooshang Akbari (assistance professor paramedic school of Mazandaran University of Medical Sciences) Email: Hooshangakbari48@yahoo.com 2) Meysam Heydari: (MSc student of operating room paramedic school of Mazandaran University of Medical Sciences) Email: Meysam10Heidari@gmail.com

What processes are involved for a request to access data/document

After submitting the request, the applicant will send the request via email to the above mentioned individuals and after specifying their goals for receiving the data, the information will be sent to them up to 10 days after the request.

Comments