

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Investigating the effect of sumac and cumin plant products in preventing nausea and vomiting after surgery

Protocol summary

Study aim

Investigating the effect of cumin and sumac products in preventing nausea and vomiting after surgery

Design

A clinical trial with a control group with parallel and double-blind randomized phase 3 trials on 120 patients, which will be used for randomization using random permutation blocks

Settings and conduct

In Pasteur Bam Hospital, 120 people are randomly selected to investigate the effect of cumin and sumac plant products on nausea and vomiting after surgery and they are divided into two treatment groups and control groups using the random permutation block method. The study uses sachets of one color and one shape to make a placebo. To give medicine, a reliable person is chosen and by using random permutation block method, it is determined what medicine each person will receive.

Participants/Inclusion and exclusion criteria

Entry requirements: age between 18 and 65 years old; Absence of stomach and intestinal ulcers.; Absence of intestinal obstruction Conditions of non-entry: occurrence of any symptoms of allergy to the herbal product during treatment; observation of any complications during treatment

Intervention groups

Investigating the effectiveness of cumin and sumac herbal product on nausea and vomiting after surgery, the subjects in the case group received 2 four-gram sachets containing sumac and cumin and the control group received 2 sachets containing corn starch and caramel as a placebo.

Main outcome variables

the severity of nausea; the number of times of vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220912055947N1**

Registration date: **2022-12-11, 1401/09/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-11, 1401/09/20**

Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

mohadeseh nasehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4434 0768

Email address

mohinasehi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sumac and cumin plant products in preventing nausea and vomiting after surgery

Public title

the effect of cumin and Kermani sumac herbal product in preventing nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1) Age between 18 and 65 years 2) Absence of underlying disease including diabetes, heart, kidney, liver, and Malori Weiss disease 3) Absence of stomach and intestinal ulcers 4) Declaration of consent to participate in the research and signing the informed consent form 5) Absence of obstruction Gut 6) Absence of sensitivity to sumac and cumin

Exclusion criteria:

The patient's unwillingness to continue the treatment Failure to respond to herbal medicine Occurrence of any symptoms of allergy to the herbal product during treatment Observing any complications during treatment Parkinson's disease

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

All eligible patients are randomly assigned to treatment and control groups using a random number table using random permutation blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to give medicine to patients in the hospital, a reliable person who has sufficient knowledge to do this work is selected and by using random permutation block method, it is determined what medicine each person will receive. The researcher and the patient do not know what medicine is received. Drug and placebo are similar in term of shape and appearance.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bam University of Medical Sciences

Street address

Pastor Hospital, Kilometer 5 Bam Baravat Road , Bam, Kerman

City

Bam

Province

Kerman

Postal code

7661961676

Approval date

2022-05-18, 1401/02/28

Ethics committee reference number

IR.MUBAM.REC.1401.027

Health conditions studied

1

Description of health condition studied

Nausea and vomiting after surgery

ICD-10 code

Y84

ICD-10 code description

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

severe nausea

Timepoint

At zero hours, 4 hours after surgery, 8 hours after surgery, 16 hours after surgery, 24 hours after surgery, the severity of nausea and frequency of vomiting during the 24-hour period are evaluated.

Method of measurement

VAS criterion

2

Description

Number of times vomiting

Timepoint

At zero hours, 4 hours after surgery, 8 hours after surgery, 16 hours after surgery, 24 hours after surgery, the severity of nausea and frequency of vomiting during the 24-hour period are evaluated.

Method of measurement

VAS criterion

Secondary outcomes

1

Description

Number of times vomiting

Timepoint

At the beginning of the study, 4, 8, 16, 24 hours after surgery

Method of measurement

VAS criterion

Intervention groups

1

Description

Intervention group: Method First, the alcoholic extract of the formulation is prepared, then the total phenolic content is measured using Fulin-Sio-Calto reagent. 0.5 ml of the extract is added to 2.5 ml of Folin Sio Calto 0.2 normal reagent, after 5 minutes 2 ml of 75 g/l sodium carbonate solution is added to it. After 2 hours, absorbance of the mixture at 760 nm wavelength is read by a spectrophotometer against a blank. To determine the amount of the sample, tannic acid standard is used to draw the calibration chart. This test is performed three times. In order to determine the amount of raw material ash, which is used to check the percentage of raw material impurities, first, 5 grams of the weighed sample is poured into a porcelain crucible that has already been cleaned, dried and weighed. then the plants are placed in an electric furnace and heated for 6 hours at a temperature of 400-500 degrees Celsius, and then the samples are placed in a desiccator and weighed after cooling. The percentage of total ash is calculated by dividing the difference of the final weight of the plant from the initial plant by the weight of the sampled material and the result is reported as a percentage. In order to determine the moisture level of the plant, 5 grams of the medicinal plant sample is placed in a clean porcelain crucible at a temperature of 100 degrees Celsius for 24 hours, and the weight loss of the sample is presented as a percentage. In order to perform microbial tests of the formulation sample, first 5 grams of phosphate buffer solution with pH = 7.2 is added to the sample, then the plate-count method according to the USP pharmacopoeia is used. In this way, one milliliter of the prepared sample is poured into a petri dish and 15 to 20 milliliters of Soybean Casein Digest Agar or Sabouraud Dextrose Agar are added to it. The plates are kept at a temperature of 30-35 degrees Celsius for one week, then the number of colonies created is counted. People in the case group receive 2 four-gram sachets containing sumac and cumin. Sachets containing sumac and cumin products are taken every 12 hours, 24 hours before surgery, along with a glass of cool water.

Category

Treatment - Drugs

2

Description

Control group: People in the control group receive 2 sachets containing corn starch and caramel as a placebo

in the same way. The way of consuming the diet is that the patients take the sachets containing placebo together with a glass of cold water, 24 hours before surgery. They eat every 12 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pastor Bam Hospital

Full name of responsible person

mohadeseh nasehi

Street address

Kerman, Bam, Kilometer 5 Bam Road, Barat, Pastor Hospital

City

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7661961676

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+98 34 4431 9400

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info@mubam.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bam University of Medical Sciences

Full name of responsible person

Sajjad Khosravi

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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

Bam 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
Bam University of Medical Sciences
Full name of responsible person
mohadeseh nasehi
Position
University student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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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