

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of olive oil consumption on surgical outcomes in open heart surgery patients

Protocol summary

Study aim

Investigating the effect of olive oil consumption on surgical outcomes in open heart surgery patients

Design

The patients were divided into two groups, 1: control, 2: test. Block random sampling is done on 110 samples, and the obtained information is analyzed using spss software.

Settings and conduct

Patients undergoing open heart surgery in Mehrgan Qazvin Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria • Non-emergency heart surgery • No history of significant digestive problems Exit criteria Unpredictable events (hemodynamic disturbances, long-term mechanical ventilation, etc.)

Intervention groups

Patients were included in the study as a sample since they were admitted to the hospital for open heart surgery. From the night of hospitalization, according to the type of diet (129), the studied parameters and the patient's conditions, 30 cc of extra virgin olive oil from Rudbar in northern Iran was added to the patient's diet at lunch and dinner (15 cc each meal) on a daily basis. 129-131). This work was done for a month since he was admitted to the hospital for surgery. Patients in the control group were requested to refrain from consuming olive oil, and to inform their respective physicians in case of consumption, in order to withdraw from the study.

Main outcome variables

1. Determining the effect of olive oil consumption on the incidence of pleural effusion in patients after open heart surgery
2. Determining the effect of olive oil consumption on constipation in patients after open heart surgery
3. Determining the effect of olive oil consumed by patients on readmission of patients after open heart surgery after consuming olive oil
4. Determining the effect of olive oil on reducing the pain of open heart surgery in ICU OH patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221005056090N1**

Registration date: **2022-11-22, 1401/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-22, 1401/09/01**

Update count: **0**

Registration date

2022-11-22, 1401/09/01

Registrant information

Name

golamreza bahrami hidaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3336 5174

Email address

bahramireza67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-19, 1401/08/28

Expected recruitment end date

2022-12-19, 1401/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of olive oil consumption on surgical outcomes in open heart surgery patients

Public title

Investigating the effect of olive oil consumption on surgical outcomes in open heart surgery patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Non-emergency heart surgery No history of significant digestive problems

Exclusion criteria:

Patients with surgery other than cabg

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method was a block random sampling method. Equal numbers were placed in two groups of test and control. First, 4 blocks were formed by choosing the letter A for the intervention group and choosing the letter B for the control group, such as (-ABBA-ABAB-BABA-BAAB-BBAA- AABB), and a total of six blocks were written on six separate sheets of paper. And it was placed in a container. Then one of the blocks was randomly selected and the first four were selected. This block was again included in the set of blocks and another block was randomly selected for the second time, and in the same way, all the participants were selected according to their entry into the study. People in the test group will be placed in the test group based on having the conditions to enter the study and their satisfaction and ability

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, in order to prevent the analyst from applying the taste of the participating groups to two groups A and B without mentioning the intervention and the witness, the data was entered into the spss software and the analyst was not aware of the allocation of people to the groups in all stages of the study.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatullah University of Medical Sciences

Street address

No. 8, Padgan Street, ally Entezari

City

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Province

Qazvin

Postal code

4573135747

Approval date

2022-05-25, 1401/03/04

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.014

Health conditions studied

1

Description of health condition studied

Coronary artery surgery

ICD-10 code

I25.7

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

Primary outcomes

1

Description

Determining the effect of olive oil consumption on the incidence of pleural effusion in patients after open heart surgery

Timepoint

The first day before surgery.The day after the operation.The second week after the operation

Method of measurement

chest x-ray

2

Description

Determining the effect of olive oil consumption on constipation in patients after open heart surgery

Timepoint

The day before the operation.Length of hospitalization.After discharge, twice a week until one month from the time of hospitalization

Method of measurement

Bristol scale

3

Description

Determining the effect of olive oil consumed by patients on readmission of patients after open heart surgery after consuming olive oil

Timepoint

One month from the time of hospitalization in case of patient referral

Method of measurement

Hospital admission

4

Description

Determining the effect of olive oil on reducing the pain of open heart surgery in ICU OH patients

Timepoint

The day before the operation.Length of hospitalization.After discharge, twice a week until one month from the time of hospitalization

Method of measurement

vas scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who were admitted to the hospital for open heart surgery were candidates to enter the study as a sample. From the night of hospitalization, according to the type of diet, the investigated parameters and the patient's conditions, the amount of 30 cc of extra virgin olive oil from Rudbar North of Iran will be added to the patient's diet at lunch and dinner (15 cc each meal) on a daily basis. Hospitalization for surgery is done for one month

Category

Diagnosis

2

Description

Control group: patients do not receive any amount of olive oil

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehrgan Qazvin Superspeciality Hospital

Full name of responsible person

Seyed Saeed Farzam

Street address

Northern Ferdowsi Street, next to the Dialysis Center of Mehrgan Hospital

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bahramireza67@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Abbas Ebadi

Street address

Sheikh Bahai Street, Baqiyatullah University, Faculty of Nursing

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ebadi1347@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

60

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Abbas Ebadi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maleeha Sadat Moid

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Yasser Saeed

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Academic staff

Latest degree

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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