Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of oral consumption of honey water (ma-ol-asal) on postoperative complications and the quality of recovery in laparoscopic cholecystectomy

Protocol summary

Study aim
Determining the effect of oral honey consumption on postoperative complications and quality of recovery in patients undergoing laparoscopic cholecystectomy

Design
Clinical trial with control group, parallel groups, double-blind, randomized on 68 patients, we will use random sequencing software to randomize

Settings and conduct
The study population includes all patients who are candidates for laparoscopic cholecystectomy and are eligible to study who have referred to hospitals in the west of Mazandaran province in 1400-1401. The study is double-blind. The prescribing physician, assistant and patient will not know any of the contents of the drugs and the drug code will be written on the file.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Laparoscopic cholecystectomy Age between 18 and 65 years To be fasting Having a BMI (body mass index) between 18 and 30 Exclusion criteria: Having nausea and indigestion Drug addiction Being pregnant while studying Having a history of allergies to honey compounds Changes in surgical procedures

Intervention groups
Intervention group: Honey syrup will be produced by NIAK Pharmaceutical Company with the permission of the Food and Drug Administration of the Ministry of Health and Medical Education. This syrup contains compounds of honey, cinnamon, ginger, saffron, cardamom, kholnjan, mastaki, jozboa and basbaseh. Control group: Placebo syrup is also prepared in Niak Pharmaceutical Company, which is packaged in bottles completely similar to honey. The placebo will contain water, acesulfame, sunset yellow and carboxymethylcellulose. Honey will be administered twice in the intervention group and placebo in the control group twice a day, twice before the operation (eight and two hours before the operation) with An anesthesiologist (15 ml) will be consulted

Main outcome variables
nausea and vomiting, pain, bloating ،quality of recovery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211018052806N1**
Registration date: **2022-06-24, 1401/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-24, 1401/04/03**
Update count: **0**

Registration date
2022-06-24, 1401/04/03

Registrant information

Name
Sahar Ghorban shamsi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 5521 3507

Email address
shamsiiisahar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral consumption of honey water (ma-ol-asal) on postoperative complications and the quality of recovery in laparoscopic cholecystectomy

Public title

The effect of oral consumption of honey water (ma-ol-asal) on postoperative complications and the quality of recovery in laparoscopic cholecystectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Laparoscopic gallbladder surgery,,, age between 18 and 65 years , NPO BMI between 18 and 30, PS patients one and two (either have no underlying disease or have controlled underlying disease) tend to Participate in the study and give informed consent

Exclusion criteria:

Having vestibular symptoms (nausea caused by ear diseases) Known gastrointestinal diseases (such as colitis, gastritis, etc.) Drug and benzodiazepine addiction Having nausea Unawareness and having psychotic symptoms Have a history of allergies to honey compounds (especially cinnamon or other plants with similar families) Being pregnant while studying Consumption of antiemetics and vomiting other than the treatment protocol The patient's inability to continue cooperating for any reason, such as loss of consciousness, death of the patient Inability of the patient to determine the severity of nausea and bloating despite the instructions Complete lack of access to the patient Changes in surgical procedures and intraoperative anesthesia for any reason

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the Restricted Randomization method of the Blocked Randomization type. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to ensure that the number of samples assigned to each of the study groups is equal in cases where intermediate analyzes are required during the sampling process. Randomization tool: We will use random sequence software (Random allocation software). In addition to simple randomization, these softwares are able to generate random sequences by blocking method. To hide the Allocation Concealment, we will use opaque sealed, sealed, opaque envelopes. This method is used to perform a random sequence on the study participants. In such a way that the assigned group is not known before the individual is assigned. The random assignment sequence and the list of blocks will be obtained by the statistics consultant with the help of random software. Use 4 blocks to create a random allocation. According to the total number of samples required for the study, which is 68 patients, 34 patients in intervention group (A), 34 patients in control group (B), 17 quadruple blocks including groups A and B are randomly designed through the software. For example, (ABAB), (BABA), (AABB), (BBAA), (BAAB) .... Based on the list of randomly prepared quadruple blocks, a trained person outside the research team is responsible for allocating patients randomly. Obtaining informed written consent, according to the 17 quadruple blocks prepared in the first stage, will be randomly assigned to the intervention group (A) and the control group (B). For example, according to the block (ABAB), each patient enters the intervention, control, intervention and control groups, respectively, after entering the study. This process continues until the last block is selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be two-way blind, so that the drug and placebo in the company are made by people who are not involved in the study and will be packaged and coded in the same way. The person doing the coding will have no role in the study until the end of the intervention. The prescribing physician, assistant, and patient will not be aware of any of the contents of the medications, and the medication code will be written on the file (double blind).

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

Mazandaran University of Medical Sciences, beginning of Vali-e-Asr Highway, Joybar Three Ways, Imam

Square
City
Sari
Province
Mazandaran
Postal code
۳۳۹۷۱-۴۸۱۵۷
Approval date
2022-05-14, 1401/02/24
Ethics committee reference number
IR.MAZUMS.REC.1401.069

Health conditions studied

1

Description of health condition studied
Laparascopic cholecystectomy
ICD-10 code
K80-K87
ICD-10 code description
بیماری های کیسه صفرا،مجاری صفراوی و پانکراس

Primary outcomes

1

Description
Nausea score based on visual analog scale
Timepoint
Upon entering the operating room, during recovery, 2 and 24 hours after surgery
Method of measurement
Visual analog scale

2

Description
Number of vomiting times based on patient observation
Timepoint
Upon entering the operating room, during recovery, 2 and 24 hours after surgery
Method of measurement
Patient observation

3

Description
Variable bloating score based on visual analog scale
Timepoint
Upon entering the operating room, during recovery, 2 and 24 hours after surgery
Method of measurement
visual analog scale

4

Description
Pain variable score based on visual analog scale
Timepoint
Upon entering the operating room, during recovery, 2 and 24 hours after surgery
Method of measurement
visual analog scale

5

Description
Recovery quality score based on QOR-40 questionnaire (40-200)
Timepoint
2, 12 and 24 hours after surgery
Method of measurement
Recovery Quality Questionnaire (QOR-40)

Secondary outcomes

1

Description
Intensity of the feeling of hunger
Timepoint
Upon entering the operating room
Method of measurement
Question from the patient

2

Description
Intense feeling of thirst
Timepoint
Upon entering the operating room
Method of measurement
Question from the patient

3

Description
Blood pressure level
Timepoint
Upon entering the operating room before induction of anesthesia, after co2 gas injection, in the recovery section, at the time of discharge from recovery and 2 hours after surgery
Method of measurement
Blood pressure manometer and vital signs monitor

4

Description
Heart rate
Timepoint
Upon entering the operating room before induction of anesthesia, after co2 gas injection, in the recovery section, at the time of discharge from recovery and 2 hours after surgery
Method of measurement
Vital Signal Monitor and Pulse Oximeter

5

Description
Shivering score based on Crossley criteria
Timepoint
In the recovery section and 2 hours after the operation

Method of measurement
Crossley criteria

6

Description
Intensity of shoulder pain
Timepoint
When discharge from recovery, 2 and 24 hours after surgery
Method of measurement
Observe and ask the patient

7

Description
Intensity of Headache, dry mouth, feeling cold, feeling weak, feeling tired before the operation
Timepoint
Upon entering the operating room
Method of measurement
Observe and ask the patient

Intervention groups

1

Description
Intervention group: Honey syrup will be produced by NIAK Pharmaceutical Company with the license of the Food and Drug Administration of the Ministry of Health and Medical Education with registration number License number: S-94-0425. This syrup contains ingredients of honey, cinnamon, ginger, saffron, cardamom, kholnjan, mastaki, jozboa and basbaseh, and the instructions for making the medicine according to the manufacturer's instructions are: 1- Honey with 2 times its amount, water poured into the container and mixed. Becomes. 2- The resulting mixture is placed at a temperature of 55 to 60 degrees Celsius and under a vacuum of 50 to 70 mm Hg to find the appropriate concentration and its volume reaches two thirds of the total initial volume. 3- From the very beginning of the heat, ginger, cinnamon, saffron, cardamom, kholnjan, mastaki, josboa and basbaseh medicines are poured into a cotton bag and hung in a container containing a mixture of water and honey for 24 hours. 4- Then the bag is taken out and the resulting material is filtered. 5. The resulting solution is packed in 200 cc bottles. 6- In every 100 cc of compound honey syrup, there are 2 grams of cinnamon, 2 grams of cardamom, 1 gram of ginger, 1 gram of kholnjan, 1 gram of saffron and 1 gram of mastic, 1 gram of gooseberry and 1 gram of basal. 7- Finally, tests of appearance characteristics, pH, density, viscosity, dry weight of the extract, microbial and fungal control are performed by NIAK Pharmaceutical Company on the final product. Assessment of quality and quality control of honey is done by NIAK company according to USP40 pharmacopoeia standard. Honey administration in the intervention group and placebo in the control group will be twice a day, so that 2 times before the operation (eight and two hours before the operation in consultation with an anesthesiologist) (15 ml), the allowable dose of the prescribed drug For an adult human, 60 kg is 30 cc.
Category
Treatment - Other

2

Description
Control group: Placebo syrup is also prepared in NIAK Pharmaceutical Company, which is packaged in bottles completely similar to honey. Placebo will contain water, acesulfame with a volume weight of 0.05 and sunset yellow with a percentage of 0.003 and carboxymethylcellulose with a content of 0.7 percent. Acesulfame is a synthetic sweetener without calories, is not metabolized in the body and is excreted intact. Artificial dye is edible. Carboxymethylcellulose acts as a thickener, preservative of shape and appearance (rheology). These compounds are used in the permitted and standard amounts in placebo. Will be given 2 times before the operation (eight or two hours before the operation in consultation with the anesthesiologist) (15 ml).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Tonekabon Hospital
Full name of responsible person
Sahar Ghorban Shamsi
Street address
at the end of Shahid Haghparast Stree, Sadatshahr
City
Ramsar
Province
Mazandaran
Postal code
4693173975
Phone
+98 11 5521 3507
Email
shamsiiisahar@gmail.com

2

Recruitment center
Name of recruitment center
Imam Sajjad Hospital in Ramsar
Full name of responsible person
Sahar Ghorban Shamsi
Street address
at the end of Shahid Haghparast Stree, Sadatshahr
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4693173975

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Ebrahim Nasiri Formi

Street address
School of Paramedical Sciences, Payambar Azam University Complex,17 km of Farahabad road.

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Sari

Province
Mazandaran

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4847193711

Phone
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Fax
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Email
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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
Mazandaran 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
Sahar Ghorban Shamsi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Others

Street address
at the end of Shahid Haghparast Stree, Sadatshahr

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Ebrahim Nasiri Formi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
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Person responsible for updating data

Contact

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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Others

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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