

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 11 5521 3507

##### Email address

shamsiisahar@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**

Laparoscopic 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

shamsiisahar@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

#### City

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#### Province

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#### Postal code

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**Email**

saharshamsii7155@gmail.com

## 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.

**City**

Sari

**Province**

Mazandaran

**Postal code**

4847193711

**Phone**

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**Fax**

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**Email**

rezanf2002@yahoo.com

**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

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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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**Position**

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Traditional Medicine

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Sahar Ghorban Shamsi

**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