Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effects of “compound Ma-ol-asal" syrup on cancer-related fatigue in gastrointestinal (GI) cancer patients who are undergoing chemotherapy

Protocol summary

Study aim
Determination of the effect of “compound Ma-ol-asal" syrup on cancer-related fatigue in gastrointestinal (GI) cancer patients who are undergoing chemotherapy

Design
A randomized, double blinded, controlled clinical trial with a parallel group, phase 3

Settings and conduct
The sample cases are the patients with GI cancer referring to oncology and chemotherapy departments of Tohid hospital of Sanandaj who have symptoms of cancer-related fatigue. In order to blind the investigator, medications are named as "A" for “compound Ma-ol-asal" syrup and B for placebo. The patients don't aware of the type of drug she or he is assigned to. . In the first visit, consent forms and questionnaires of the fatigue severity based on Visual Analogue Fatigue Scale (VAS), Fatigue Severity Scale (FSS) and the Cancer Fatigue Scale (CFS) are completed. After two weeks, patients are followed up by phone and after 4 weeks, patients are re-visited and questionnaires of fatigue severity will be completed again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1.Age between 18- 70 years old; 2. GI cancer (pathologically diagnosed).3.Undergoing chemotherapy 4. Hemoglobin level at least 10g/dl Exclusion criteria: 1. Heart disease with unstable conditions 2. Liver disease with unstable conditions .3. Positive history of hypersensitivity to each component of the “compound Ma-ol-asal" syrup., 4. Serious accompanying disease. .

Intervention groups
Group A: patients with GI cancer-related fatigue receiving “compound Ma-ol-asal" syrup, 10 cc three times daily. Group B: patients with GI cancer-related fatigue receiving placebo, 10 cc three times daily.

Main outcome variables
1. The mean of score of "Visual Analogue Fatigue Scale", 2.The mean of score of "Fatigue Severity Scale", 3. The mean of score of "The Cancer Fatigue Scale"

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191211045693N1**
Registration date: **2022-08-20, 1401/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-20, 1401/05/29**
Update count: **0**

Registration date
2022-08-20, 1401/05/29

Registrant information

Name
ata amani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2023-07-23, 1402/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

Effects of “compound Ma-ol-asal" syrup on cancer-related fatigue in gastrointestinal (GI) cancer patients who are undergoing chemotherapy

Public title

Effects of “compound Ma-ol-asal" syrup on cancer-related fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1.Age between 18- 70 years old 2. GI cancer (pathologically diagnosed) 3.Undergoing chemotherapy 4. Hemoglobin level at least 10g/dl 5. Hematocrit level at least 30% . 6. No clinical symptom of hypothyroidism 7. Visual Analogue Fatigue Scale (VAS)>=4

Exclusion criteria:

1. Heart disease with unstable conditions 2. Liver disease with unstable conditions 3. Disabling pulmonary disease 4. Positive history of hypersensitivity to honey and its compounds 5. Positive history of hypersensitivity to each component of the “compound Ma-ol-asal" syrup. 6. Uncontrolled pain. 7. An individual who uses treatment due to known psychiatric disease 8.Pregnancy. 9. Simultaneous use of drugs that affect fatigue. 10. kidney disease with unstable conditions 11. Severe infection 12. Serious accompanying disease.

Age

From **18 years** old to **78 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

In this study, the restricted randomization method of block randomization is used. Blocking is used to balance the number of samples assigned to each of the study groups. The randomization method was performed using balanced block randomization and in the form of 4 blocks using the computer. Each drug is labeled with a number from 1 to 120. Patients were divided into two groups for the trial: the first group (60 people) was the intervention group and the second (60 people) was the control group (placebo group). Both groups were equally divided in terms of characteristics and coordinated conditions. The control group is assigned to "A" and the intervention group to "B", and then these two groups are divided into 6 blocks of 4: (1) AABB, (2) BBAA, (3) ABAB, (4) BABA, (5) AB BA, (6) BAAB . These blocks are randomly stacked together by a computer to form a chain of random groups (e.g. B B A A A A B B A B A B B A B A A B B A B A A B) Patients then enter these groups in the order of enrollment. For randomization, a randomization tool for random sequence software called Random allocation software is used. In addition to simple randomization, this software is also able to generate random sequences by the block generation method. For concealment, we use allocation concealment, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Jollab or placebo bottles are produced with the same shape and color and after coding with a random sequence, each of the random sequences created is recorded on a label. The labels are stuck on Jollab or placebo bottles. Participants will receive the labeled bottles

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, both Jollab syrup and placebo are made by the pharmacist in the laboratory and dumped and coded in similar bottles that only the pharmacist knows about the codes and in the same way it will be given to researchers and basis on randomization finally for participants both so the researcher and the participant are blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yaman Ave., Sh. Aarabi Ave., Shahid Beheshti University of Medical Sciences

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Province

Tehran

Postal code

1985717443

Approval date

2020-06-07, 1399/03/18

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.260

Health conditions studied

1

Description of health condition studied

Neoplastic (malignant) related fatigue

ICD-10 code

R53.0

ICD-10 code description

Neoplastic (malignant) related fatigue

Primary outcomes

1

Description

Score of Fatigue Severity "Visual Analogue Fatigue Scale"

Timepoint

Week 0 (before the start of the intervention) and week 4 (after the start of the intervention)

Method of measurement

Using Visual Analogue Fatigue Scale questionnaire

2

Description

Score of "The Cancer Fatigue Scale"

Timepoint

The weeks of 0 and 4 after treatment

Method of measurement

The Cancer Fatigue Scale questionnaire

Secondary outcomes

1

Description

dyspepsia

Timepoint

Week 0 (before the start of the intervention) and week 4 (after the start of the intervention)

Method of measurement

Likert scale

Intervention groups

1

Description

Intervention group:In addition to all the standard and required medicines, patients with GI cancer-related fatigue receiving “compound Ma-ol-asal" syrup that is made by Niak Pharmaceutical Company, 10 cc three times daily for four weeks;

Category

Treatment - Drugs

2

Description

Control group: In addition to all the standard and required medicines, patients with GI cancer-related fatigue receiving placebo that is made by Niak pharmaceutical company , 10 cc three times daily for four weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid hospital, Oncology and Chemotherapy clinic

Full name of responsible person

Ata Amani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sponsor Vice chancellor for research, Shahid Beheshti University of Medical Sciences

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
MD, PhD student

Latest degree
Medical doctor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The study has not started yet, and the progress of the work and the data cannot be predicted so a decision will be made after the completion of the project.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available