

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the efficacy of Pistacia atlantica gum on clinical symptoms of diabetic patients with gastroparesis

Protocol summary

Summary

Gastroparesis is a disorder of delayed gastric emptying in the absence of mechanical obstruction that is more common in diabetic patients. Pistacia atlantica gum is one of the effective herbs in the treatment of stomach disorders. The aim of this study is to investigate the effect of Pistacia atlantica gum on diabetic gastroparesis symptoms. The target population are type 1 or 2 diabetic patients older than 18 years with the clinical symptoms of gastroparesis who are referred to the clinic of Imam Reza hospital. Patients, who are evaluated about other criteria by a gastroenterologist and endocrinologist and are willing to participate, enroll in the study. The sample size is 48. The patients will randomly be divided into two groups by block randomization method. In both groups, appropriate dietary advice with diabetic gastroparesis is given to the patients. In addition, patients in intervention group receive Pistacia atlantica gum and the control group receive placebo. This study is done Triple blind. Symptoms will be recorded by GCSI standard questionnaire (Gastroparesis cardinal symptom index). The questionnaire evaluates six groups of symptoms, including nausea and vomiting, filling of fullness and early satiety, bloating, upper abdominal pain, lower abdominal pain, heartburn and belching. Hematology and biochemistry blood tests including Complete blood count, Fasting blood sugar, Glycated hemoglobin, Triglycerides, Cholesterol, Low-density lipoprotein, High-density lipoproteins, Aspartate aminotransferase, Alanine aminotransferase, creatinine and Blood urea nitrogen will be done at baseline and 4 weeks later to assess the patients condition and the possible treatment side effects and also the effect of gum on the control of blood sugar and fat and also liver and renal parameters in patients with diabetic gastroparesis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110630739N1**

Registration date: **2016-12-25, 1395/10/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-25, 1395/10/05

Registrant information

Name

Fatemeh Mahjoub

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2189

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mahjoubf911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the efficacy of Pistacia atlantica gum on

clinical symptoms of diabetic patients with gastroparesis

Public title

The effect of Pistacia atlantica gum on diabetic gastroparesis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type 1 or 2 diabetic patients older than 18 years with clinical symptoms of gastroparesis for more than 3 months that determined by GCSI questionnaire. Exclusion criteria: organic disorders in the upper endoscopy in patients with risk factors such as unexplained weight loss, odynophagia, dysphagia, gastrointestinal cancer, family history for gastrointestinal cancer and age over 55 years; evidence of mechanical obstruction of the stomach or bowel; History of gastrectomy, gastric bypass, gastroplasty, pyloroplasty and vagotomy; Patients with heart failure, kidney failure, hepatitis or liver failure; Uncontrolled thyroid disorders; Endoscopic botulinum toxin injection in the pylorus in the past 6 months; Patients who have been treated with electrical stimulation of the stomach; Consumers of medicines that induce delayed gastric emptying such as Acarbose, Miglitol, Exenatid, benzodiazepines, calcium channel blockers, narcotics, alpha-2 adrenergic receptor agonists such as clonidine, tricyclic antidepressants, dopamine agonists, cholinergic muscarinic receptor antagonists, Octreotide, phenothiazines, cyclosporine; Patients with dry mouth and dry tongue; History of allergy to Pistacia atlantica; Pregnancy and lactation; Patient's unwillingness to continue the project; incidence of possible side effects

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will randomly be divided into two categories, A and B, using blocking method by create of 4 blocks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ethics committee of Mashhad University of Medical Sciences, Qureshi Building, Daneshgah Ave, Mashhad.

City

Mashhad

Postal code

00985138411538

Approval date

2016-10-29, 1395/08/08

Ethics committee reference number

IR.MUMS.REC.1395.379

Health conditions studied

1

Description of health condition studied

Diabetic gastroparesis

ICD-10 code

E14.8

ICD-10 code description

Unspecified diabetes mellitus with unspecified complications

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

At baseline and after 1,2,3,4 and 8 weeks

Method of measurement

GCSI questionnaire

2

Description

Postprandial fullness/early satiety

Timepoint

At baseline and after 1,2,3,4 and 8 weeks

Method of measurement

GCSI questionnaire

3

Description

Bloating

Timepoint

At baseline and after 1,2,3,4 and 8 weeks

Method of measurement

GCSI questionnaire

4

Description

Upper abdominal pain

Timepoint

At baseline and after 1,2,3,4 and 8 weeks

Method of measurement

GCSI questionnaire

5

Description

Lower abdominal pain

Timepoint

At baseline and after 1,2,3,4 and 8 weeks

Method of measurement

GCSI questionnaire

6

Description

Heartburn/regurgitation

Timepoint

At baseline and after 1,2,3,4 and 8 weeks

Method of measurement

GCSI questionnaire

Secondary outcomes

1

Description

Low-density lipoprotein

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

2

Description

High-density lipoprotein

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

3

Description

Aspartate aminotransferase

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

4

Description

Alanine aminotransferaseh

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

5

Description

Blood urea nitrogen

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

6

Description

Glycated hemoglobin

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

7

Description

Triglycerides

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

8

Description

Cholesterol

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

9

Description

Complete blood count

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

10

Description

Fasting blood sugar

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

11

Description

Creatinine

Timepoint

Baseline, the end of the study

Method of measurement

Blood test

Intervention groups

1

Description

In the intervention group, patients are provided with appropriate dietary advice. In addition, Pistacia Atlantica in the form of 2 gram Chewing gum is given to the patients, twice a day, after meals, for one month.

Category

Treatment - Drugs

2

Description

Control group: in this group, the diet suitable for diabetic gastroparesis and Placebo will be given to the patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic for gastrointestinal diseases, Imam Reza (AS) Hospital

Full name of responsible person

Dr. Kambiz Akhavan Rezayat, Gastroenterologist, Assistant professor

Street address

Special clinic for gastrointestinal diseases, Imam Reza (AS) Hospital, Ibn Sina St, Mashhad.

City

Mashhad

2

Recruitment center

Name of recruitment center

Special clinic for endocrine diseases, Imam Reza (AS) Hospital

Full name of responsible person

Dr. Masoud Mohebbi, Endocrinologist, Assistant professor

Street address

Special clinic for endocrine diseases, Imam Reza (AS) Hospital, Ibn Sina St, Mashhad.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Vice chancellor for research of Mashhad University of Medical Sciences, Qureshi Building, Daneshgah Ave, Mashhad.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of complementary and Persian medicine of Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh mahjoub

Position

PhD student of Iranian Traditional Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Mashhad University of Medical Sciences, Imam Reza (AS) Hospital

Full name of responsible person

Dr. Kambiz Akhavan Rezayat

Position

Gastrointestinal specialist, Assistant professor

Other areas of specialty/work

Street address

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Postal code**Phone**

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School of complementary and Persian medicine of Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Mahjoub

Position

PhD student of Iranian Traditional Medicine

Other areas of specialty/work**Street address**

School of complementary and Persian medicine,

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty