Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical traial 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 condotion 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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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 traial 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
Street address
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 medicineof Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh mahjoub
Position
PhD student of Iranian Traditional Medicine
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Person responsible for scientific inquiries

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Mashhad University of Medical Sciences, Imam Reza (AS) Hospital
Full name of responsible person
Dr. Kambiz Akhavan Rezayat
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Gastrointestinal specialist, Assistant professor
Other areas of specialty/work

Street address
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Person responsible for updating data

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Full name of responsible person
Fatemeh Mahjoub
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mahjoubf911@mums.ac.ir
Web page address

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