

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Exploring Intra-gastric Botulinum Toxin Injections: A Prospective study on the rate of Weight Loss in Overweight and Obese Patients

Protocol summary

Study aim

Investigating the effect of intra-gastric botulinum toxin injection on weight loss in obese patients

Design

Clinical trial with a control group, non-randomized, single-center, single blind, with parallel groups, phase 3 on 60 patients

Settings and conduct

This study will be conducted in the gastroenterology clinic and the nutrition clinic of Taleghani Hospital. The participants will be placed in the intervention and control groups based on their choice. Patients in the intervention arm will receive 5 cc containing 500 units of botulinum toxin A (Masport) diluted in 10 ml of saline. A total of 50 units of botulinum toxin is injected at 10 sites in the stomach, targeting the antrum 5 cm above the pylorus (3 points), the body (5 points), and the fundus (2 points). All patients in the intervention and control groups are given specific calorie-restricted diets. Subsequent visits are scheduled at 4-week intervals for a total of 3 months. the study is single blinded study in which the outcome assessor and the analyst are blinded.

Participants/Inclusion and exclusion criteria

Entry criteria: body mass index between 25 and 40; absence of other comorbidities; absence of contraindications for administering botulinum toxin. Exclusion criteria: history of bariatric surgery; allergy to Mesport; pregnancy; liver cirrhosis; eating disorders; cardiovascular or pulmonary disease; diabetes

Intervention groups

The intervention group receives intra-gastric botulinum toxin injection under endoscopic guidance in the amount of 5 cc containing 500 units of botulinum toxin A. They also receive a low-calorie diet. The control group is subjected to a controlled low-calorie diet.

Main outcome variables

Weight, body mass index, waist circumference, hip circumference, waist-to-hip ratio, arm circumference, possible complications, patients' satisfaction with each

method, lipid profile, blood glucose, HbA1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230408057842N2**

Registration date: **2023-10-22, 1402/07/30**

Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**

Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name

Pardis Ketabi Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2525

Email address

ketabimoghadam.p@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Exploring Intragastric Botulinum Toxin Injections: A Prospective study on the rate of Weight Loss in Overweight and Obese Patients
Public title	The effect of botulinum in obese patients
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Body mass index (BMI) between 25-39.9 kg/m² Willingness to participate in the intervention Absence of any other comorbidity Absence of any contraindications for botulinum toxin administration Exclusion criteria: Participants with a history of previous bariatric surgery BMI ≥ 40 kg/m² Known allergy to any ingredients in Masport or allergic reaction Pregnancy or lactation Known pre-existing neuromuscular disorders or peripheral motor neuropathic disease (e.g. amyotrophic lateral sclerosis, motor neuropathy) Patients with known liver cirrhosis or known esophageal/gastric varices Known eating disorders Known major cardiovascular or pulmonary conditions Diabetes Pathologic changes of the esophagus/stomach/duodenum demonstrated on endoscopy (esophagitis, peptic ulcers, cancer) Known alcohol or drug abuse
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	• Outcome assessor • Data analyser
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Single blinded
Blinding description	In this study, the person evaluating the outcomes in both intervention and control groups does not know which group each patient is assigned to. Also, the names of the patients along with their other information are provided to the analyst in coded form to avoid any bias.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	research ethic committee of research institute for gastroenterology and liver disease
Street address	Arabi street, Velenjak
City	Tehran
Province	Tehran
Postal code	1985717443
Approval date	2023-09-04, 1402/06/13
Ethics committee reference number	IR.SBMU.RIGLD.REC.1402.002
Health conditions studied	
1	
Description of health condition studied	Overweight and obesity
ICD-10 code	E66
ICD-10 code description	Overweight and obesity
Primary outcomes	
1	
Description	weight
Timepoint	before the intervention and three months later
Method of measurement	scales
2	
Description	body mass index
Timepoint	before the intervention and three months later
Method of measurement	Height to weight ratio formula
3	
Description	waist circumference
Timepoint	before the intervention and three months later
Method of measurement	meter

4

Description

hip circumference

Timepoint

before the intervention and three months later

Method of measurement

meter

5

Description

waist-to-hip ratio

Timepoint

before the intervention and three months later

Method of measurement

waist-to-hip ratio formula

6

Description

arm circumference

Timepoint

before the intervention and three months later

Method of measurement

meter

7

Description

lipid profile

Timepoint

before the intervention and three months later

Method of measurement

laboratory kits

8

Description

blood glucose

Timepoint

before the intervention and three months later

Method of measurement

laboratory kits

9

Description

HbA1c

Timepoint

before the intervention and three months later

Method of measurement

laboratory kits

Secondary outcomes

1

Description

side effects

Timepoint

before the intervention and three months later

Method of measurement

Patient examination and history

2

Description

patients' satisfaction with each method

Timepoint

before the intervention and three months later

Method of measurement

Questionnaire of satisfaction with weight loss program

Intervention groups

1

Description

Intervention group: The intervention group receives intragastric botulinum toxin injections under endoscopic guidance. Patients in the intervention arm will receive 5cc containing 500units of Botulinum Toxin A (Masport; MasoonDarou Pharmaceutical Company; Iran) diluted to 10mls of saline. Endoscopy will be performed using a single-lumen gastroscope. Injection of the solution will be done using a 23Gauge Interject needle catheter. 10 separate injections of 1.5ml each will be performed in a concentric ring 5cm apart. A total of 50 units of botulinum toxin are injected at 10 sites in the stomach, targeting antrum 5cm above the pylorus (3 points), body (5 points), and fundus (2 points). Also, they receive a limited diet with specific calories.

Category

Treatment - Surgery

2

Description

Control group: Participants receive standardized nutritional counseling by a registered dietitian. They are given specific calorie-restricted diets that aim to lose 0.5-1 kg of weight per week.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

gastroenterology and liver disease clinic, Taleghani hospital

Full name of responsible person

Mohammad Javad Ehsani Ardakani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Arabi street, Velenjak

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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

Alireza Zahedi

Position

Gastroenterologist assistant

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

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Full name of responsible person

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Only the information related to the study protocol,

statistical analysis plan and clinical study report will be made available to the requestors (and not publicly) to other researchers for guidance for further studies.

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Researchers, students and professors in the field of digestion and nutrition

Under which criteria data/document could be used

For use in further research and if the source is cited

From where data/document is obtainable

Corresponding author Dr. Pardis Ketabi Moghadam
ketabimoghadam.p@sbm.ac.ir

What processes are involved for a request to access data/document

Send a request via email to the responsible author and mention the reason for the request and how to use the data

Comments