Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effectiveness of sugar-free chewing gum in reducing the snaking in patients with a history of sleeve gastrectomy and classic gastric bypass

Protocol summary

Study aim
Evaluation of the effect of chewing sugar-free gum on the snaking after gastrectomy sleeve and classic bypass

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 100 patients. The rand function of the Excel software was used for randomization.

Settings and conduct
In this clinical trial with a control group, which is performed on 116 patients complaining of snaking after obesity surgery, patients refer to Rasool-e Akram Obesity Center in Tehran and are divided into two groups: sugar-free gum and the control group. Statistical analyzer and outcome assessor are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: History of Gastric Sleeve or classic bypass, Snaking after gastric sleeve or classic bypass, consent to participate in the study. Exclusion criteria: Age more than 60 years, history of dental problems resulting in disability to chew properly

Intervention groups
Intervention group: It is recommended to chew sugar-free gum regularly and four hours a day in the form of four one-hour intervals between meals to the patients for two months. Control group: Do not receive chewing gum.

Main outcome variables
Reducing the snaking; Weight loss after bariatric surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190128042520N3**
Registration date: **2021-11-02, 1400/08/11**
Registration timing: **prospective**
Last update: **2021-11-02, 1400/08/11**
Update count: **0**

Registration date
2021-11-02, 1400/08/11

Registrant information

Name
Mohammad Kermansaravi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 8809 5451

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-12-23, 1401/10/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of sugar-free chewing gum in reducing the snaking in patients with a history of sleeve gastrectomy and classic gastric bypass

Public title
The effect of sugar-free chewing gum on reducing snaking after weight loss surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

History of Gastric Sleeve or classic bypass Snaking after gastric sleeve or classic bypass Consent to participate in the study

Exclusion criteria:

Age more than 60 years History of dental problems resulting in disability to chew properly

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is used; Blocking should be used to balance the number of samples assigned to each of the study groups. In this way, because we have two intervention groups, equal blocks of 4 are used and we create all possible blocks of 4, and then we randomly select a number of blocks with Excel software. Because the number of sample sizes in this study is 116 people (58 people in each group), 15 blocks of 4 using Excel software are needed. Also, in order to observe the concealment of the randomization sequence, this sequence is given to a person outside the study who has no involvement in the study, who announces the sequence of patients in the study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor is unaware of the allocation of patients in the two groups and the statistical analyst receives the groups as codes A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ehtics Committee of Iran University of Medical Sciences

Street address

Fifth floor, Headquarter., Iran university of Medical Sciences., between Chamran and Sheikh Fazlollah., Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.IUMS.REC.1400.009

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Snaking changes

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Interview with patients

Secondary outcomes

1

Description

Weight change

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Scale

Intervention groups

1

Description

Intervention group: Intervention group is recommended to chew sugar-free gum (Biodent company of Iran) regularly and four hours a day in the form of four one-hour intervals between meals to the patients for two months

Category

Prevention

2

Description
Control group: Do not receive chewing gum.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital Obesity Clinic
Full name of responsible person
Mohammad Kermansaravi
Street address
Sattarkhan street, Niyayesh street, Rasool-e Akram hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
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Position
Assistant professor
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Full name of responsible person
Mohammad Kermansaravi

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Fax

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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