

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the safety and efficacy and of sodium pentaborate pentahydrate in people with overweight and obesity: a randomised, double-blind, placebo-controlled phase 1/2 trial

Protocol summary

Study aim

Evaluation of the safety and effectiveness of sodium pentaborate pentahydrate in overweight and obese people

Design

A Phase 1-2 Randomized, Double-Blind, Placebo-Controlled Clinical Trial on 120 participants. Using balanced block randomization, patients will be enrolled in one of the two groups

Settings and conduct

This study will be conducted in hospitals affiliated with Tabriz University of Medical Sciences. Individuals over 18 years of age with a body mass index (BMI) ≥ 30.0 kg/m² or a BMI ≥ 27.0 kg/m² in the presence of hypertension or dyslipidemia will be selected. Participants were randomized (6:1) to oral administration of NaB once daily (200, 400, 600, 800, 1000 mg), or the corresponding placebo, using balanced block randomization. The primary objective will be the relative change in body weight (percentage) from baseline at week 12. Adverse effects will be carefully monitored and evaluated in terms of physical examinations and laboratory procedures.

Participants/Inclusion and exclusion criteria

Individuals with body mass index (BMI) ≥ 30.0 kg/m² or BMI ≥ 27.0 kg/m² with hypertension or dyslipidemia will be included in the study. People with a history of diabetes, obesity caused by endocrine disorders, or a weight change of more than 5 kg in the last three months, or receiving medication for weight loss, will not be included.

Intervention groups

Five intervention groups (use of sodium pentaborate pentahydrate once a day in one of 5 doses (200, 400, 600, 800, 1000 mg)) and one placebo group will receive drugs of the same shape, smell and color.

Main outcome variables

Change of body weight compared to base weight;
Proportion of people with weight loss $\geq 5\%$ of the initial body weight; Proportion of people with weight loss $\geq 10\%$ of the initial body weight; waist to hip ratio; BMI change (kg/m²); HbA1c change; Changes in fasting plasma glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220614055167N3**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Saeid Safiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3332 7195

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

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
Evaluation of the safety and efficacy and of sodium pentaborate pentahydrate in people with overweight and obesity: a randomised, double-blind, placebo-controlled phase 1/2 trial

Public title
Safety and efficacy and of sodium pentaborate pentahydrate in people with overweight and obesity

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥ 18 years at the time of signing the informed consent A non-pregnant female participant or a male participant who has been surgically sterilized (vasectomy) or is willing to use appropriate contraceptive methods during the trial (until the end of the trial) Body mass index (BMI) ≥ 30.0 kg/m² or BMI ≥ 27.0 kg/m² in the presence of hypertension or dyslipidemia (treated or untreated, assessed at the discretion of the investigator)
Exclusion criteria:
Glycosylated hemoglobin (HbA1c) ≥ 48 mmol/mol (6.5%) as measured by the laboratory at screening History of type 1 or type 2 diabetes Treatment with glucose-lowering drug(s) within 90 days prior to screening Obesity due to endocrine disorders (eg, Cushing's syndrome) A change in body weight of more than 5 kg within 90 days prior to screening regardless of medical record Treatment with any medication proven to control weight within 90 days prior to screening Treatment of obesity with surgery or a weight loss device. However, the following are permitted: (1) liposuction and/or abdominoplasty, if performed more than one year prior to screening; (2) lap banding, if the banding was removed more than 1 year before the screening. (3) intragastric balloon, if the balloon was removed more than 1 year before the screening. or (4) duodenal-jejunal bypass sleeve, if the sleeve was removed more than 1 year before screening Uncontrolled thyroid disease, defined as TSH > 4.78 mIU/L or 1.5 times the upper limit of normal, which is measured by the laboratory in the screening Undertreated hypertension, defined at screening as systolic ≥ 180 mmHg or diastolic ≥ 110 mmHg Presence or history of cardiovascular disease, including stable and unstable angina pectoris, myocardial infarction, transient ischemic attack, stroke, cardiac decompensation, clinically significant arrhythmias, or clinically significant conduction disturbances The participant is currently classified as having New York Heart Association Class IV heart failure Surgery planned during the trial period, excluding minor surgery, at the discretion of the investigator Known or suspected abuse of alcohol or recreational drugs Known

or suspected hypersensitivity to test product(s) or related products Participation in another clinical trial within 90 days prior to screening Personal or first-degree relative history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma Presence of acute pancreatitis within 180 days before screening History or presence of chronic pancreatitis Any impairment, unwillingness, or disability, not covered by any of the other exclusion criteria, that in the opinion of the investigator may compromise the participant's safety or compliance with the protocol.

Age
From **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Using block randomization, patients will be assigned to intervention groups or placebo groups. The randomization sequence will be determined by one of the individuals who did not participate in the current research. It is necessary to explain that the aforementioned randomization method reduces the possibility of predicting and manipulating the randomization process by people to zero and will lead to the balance of the size of the groups during and at the end of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients will receive the boxes sealed with 10-digit codes and will receive the original drug or placebo, and they will not be aware of the type of received material. The researcher will ensure the blinding of the patients. Also, doctors, researchers, and those responsible for the implementation of the project will not be aware of the type of medicine received by the patients until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Azadi St, Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166/15731

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.TBZMED.REC.1401.1014

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

The relative change of body weight compared to the base weight (%)

Timepoint

Screening, randomization and weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Scale

Secondary outcomes

1

Description

Proportion (%) of people with weight loss $\geq$ 5% of initial body weight

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Scale

2

Description

Proportion (%) of people with weight loss $\geq$ 10% of initial body weight

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Scale

3

Description

Relative change in waist circumference compared to baseline

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Tape measure

4

Description

Relative change in body mass index compared to baseline

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Scale and tape measure

5

Description

Relative change of waist to hip circumference compared to baseline

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Tape measure

6

Description

Hemoglobin A1c level

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

HbA1c Reagent Kit

7

Description

Fasting blood glucose

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Glucometer

8

Description

Insulin level

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Human Insulin ELISA Test Kit

9

Description

Systolic and diastolic blood pressure

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Digital manometer

10

Description

High density lipoprotein (HDL) levels

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Laboratory kits

11

Description

Low density lipoprotein (LDL) levels

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Laboratory kits

12

Description

Triglyceride level

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Laboratory kits

13

Description

Total cholesterol levels

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Laboratory kits

14

Description

High-sensitivity C-reactive protein level

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Laboratory kits

15

Description

Quality of life related to general health

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Short-Form 36 (SF-36) v2.0 acute score change

16

Description

Weight-related quality of life

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Three-Factor Eating Questionnaire Revised 18-item version 2 score change (TFEQ-R18v2)

17

Description

Adverse events

Timepoint

Weeks 2, 4, 6, 8, 10, 12, 16

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Capsules containing sodium pentaborate pentahydrate 200 mg

Category

Treatment - Drugs

2

Description

Intervention group: Capsules containing sodium pentaborate pentahydrate 400 mg

Category

Treatment - Drugs

3

Description

Intervention group: Capsules containing sodium pentaborate pentahydrate 600 mg

Category

Treatment - Drugs

4

Description

Intervention group: Capsules containing sodium pentaborate pentahydrate 800 mg

Category

Treatment - Drugs

5

Description

Intervention group: Capsules containing sodium pentaborate pentahydrate 1000 mg

Category

Treatment - Drugs

6

Description

Control group: Placebo capsules

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Saeid Safiri

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Saeid Safiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All of the information will be available to all after publishing without the personal information of participants.

When the data will become available and for how long

After publishing the papers

To whom data/document is available

All researchers that are confirmed by the principal investigator

Under which criteria data/document could be used

All of the data will be available except the personal information of the participants

From where data/document is obtainable

Applicants can initially communicate with the principal investigator's email that is available in this protocol, and if there is no response within a week, a reminder email will be sent again. If they still do not receive an answer, they can call the relevant contact number or send a letter to the listed postal address.

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

It is evaluated by the team and the principal investigator will inform those who requested

Comments