

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study of water pre- load Effect on the levels of Glycemic index, lipid profile and serum Copeptin in Diabetic Patients type

Protocol summary

The outcomes of this study can help improve the condition of diabetics

Study aim

1- Determining the effect of water intake before meals on the BMI, energy and received Macronutrients in patients with type 2 diabetes before and after intervention compared to the control group 2. Determination of the effect of water intake before meals on the mean glycemic index (blood glucose, serum insulin and insulin resistance, HbA1C), serum copeptin, serum lipid profile in type 2 diabetes patients before and after intervention compared to the control group

Design

A clinical trial with a control group - with parallel, double blind, randomized groups

Settings and conduct

From the bu-ali diabetes clinic in Zahedan, we randomly divided 40 patients into two groups and examined the relevant laboratory data before and after the intervention (water intake recommendation). The patient is not aware of the contents of the intervention. The intervention provided is the same in every respect, and the statistician has no information about the members of the groups for the purpose of blindness.

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: All people with type 2 diabetes have been diagnosed with fixed medication during the intervention, aged between 30-65 years. **EXCLUSION criteria:** Breastfeeding, Heart disease, History of heart failure during the past 3 months, MI, Acute / Chronic Liver Diseases other than Fatty Liver, Dyslipidemia (Creatinine > 1.62 mg / dl) Hyperthyroidism, Hyperthyroidism, The use of NSAIDs, insulin therapy, and depression medications.

Intervention groups

In the intervention group, people are asked to take 500 cc of water before the main meal and in the control group it is recommended that they do not consume water before eating (in fact, it does not recommend or emphasize water intake)

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180910040986N1**

Registration date: **2018-10-04, 1397/07/12**

Registration timing: **prospective**

Last update: **2018-10-04, 1397/07/12**

Update count: **0**

Registration date

2018-10-04, 1397/07/12

Registrant information

Name

gohar sedaghat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3620 4807

Email address

g.sedaghat@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of water pre- load Effect on the levels of Glycemic index, lipid profile and serum Copeptin in Diabetic Patients type

Public title

The effect of Pre-meal water on the treatment of diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All people with type 2 diabetes have been diagnosed Use of fixed drugs during the intervention

Exclusion criteria:

Lacking and Pregnancy No history of heart disease, history of heart failure during the past 3 months, myocardial infarction, acute / chronic liver disease, but not fatty liver, kidney impairment (Creatinine> 1.62 mg / dl) hyperthyroidism and hypothyroidism Use of NSAIDs treatment with Insulin Use of depressant drugs

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is based on the spss statistical software based on the records and the sample size of the sample envelope, and then we put the case and control group sheets according to the output of the software in the envelope and we use it for sampling.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is unaware of which of the study groups (it is said that it is not known to the two groups whose tectacide is not based on the general diet) and the statistician is not aware of which group of data is available.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

no 7.,ladan blvd.,beheshti town

City

shiraz

Province

Fars

Postal code

71896-57936

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.ZAUMS.REC.1397.202

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

serum copeptin

Timepoint

Before the intervention and 2 months later

Method of measurement

laboratory kit

Secondary outcomes

1

Description

serum insulin

Timepoint

The beginning and the end of the intervention

Method of measurement

laboratory kit

Intervention groups

1

Description

Intervention group: The group is advised to consume 500 cc water before each meal

Category
Lifestyle

2

Description

Control group: A group that refuses to consume water before eating, and no recommendation is made for water intake

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
bu-ali diabetes clinic
Full name of responsible person
Sedaghat Gohar
Street address
no 8., 7 ladan Blvd., Beheshti town
City
SHIRAZ
Province
Fars
Postal code
7189657936
Phone
+98 71 3620 4807
Email
g.sedaghat@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Farzaneh Montazeri Far
Street address
Zahedan University Of Medical Science,.Dr Hesabi Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 1341 6708
Email
montazery@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Gohar Sedaghat
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
No.8, ladan7 street, beheshti town
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Person responsible for scientific inquiries

Contact

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Fax**Email**

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Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

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Position

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

Yes - There is 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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The main variables information will be shared

When the data will become available and for how long

Since year 2020

To whom data/document is available

Researchers working in scientific and research centers

Under which criteria data/document could be used

Use of data in other researches may be allowed

From where data/document is obtainable

To receive any kind of information, please contact the author of the project by e-mail "vazheh4@yahoo.com"

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

After receiving the email, can find the correct documentation after a month.

Comments