

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Assessment of the effect of oral pyridoxine hydrochloride supplement on anthropometric measurements, body composition, visceral adiposity index, glycemic and lipidemic risk factors and serum levels of leptin and adiponectin in obese and overweight women

Protocol summary

Study aim

Determination of the effect of oral pyridoxine hydrochloride supplement on anthropometric measurements, body composition, visceral adiposity index, glycemic and lipidemic risk factors and serum levels of leptin and adiponectin in obese and overweight women

Design

The present study is a clinical trial of phase 3, randomized, double blind and parallel, which will be done on 44 obese and overweight women who have criteria for entering the study. Patients would be randomly allocated to the intervention or control groups using random number tables and each participant is being assigned a code.

Settings and conduct

This study will be carried out on Ahvaz medical personnel. At the beginning and the end of the study, anthropometric measurements, body composition and visceral fat index are examined and Fasting blood samples are also taken to determine glycemic and lipidemic profile and serum leptin and adiponectin levels. Diet and physical activity are recorded by the 24-hour recall and the International Physical Activity Inventory.

Participants/Inclusion and exclusion criteria

Inclusion criteria: female; age between 18-50 years old; body mass index is over 25 kg / m²; no changes in weight over 5 kg over the past 3 months; no history of diabetes, cardiovascular, brain, kidney, liver, respiratory, digestive, thyroid; do not use drugs that affect lipid profile and blood glucose and contraception and supplements including antioxidants, minerals, omega 3 and B6. Exclusion criteria: lack of patient collaboration at each stage of intervention; pregnancy during intervention; identify any of the diseases or use the drugs mentioned; start a weight loss die.

Intervention groups

Intervention group: pyridoxine hydrochloride Supplement, 2 pills 40 mg per day for 8 weeks. Control group: placebo, starch, 2 pills 40 mg per day for 8 weeks.

Main outcome variables

Fasting Glucose; insulin; insulin resistance; lipid profile; serum leptin and adiponectin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181002041206N1**

Registration date: **2018-10-31, 1397/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-31, 1397/08/09**

Update count: **0**

Registration date

2018-10-31, 1397/08/09

Registrant information

Name

Fateme Mirzaey

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3722 2651

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of oral pyridoxine hydrochloride supplement on anthropometric measurements, body composition, visceral adiposity index, glycemic and lipidemic risk factors and serum levels of leptin and adiponectin in obese and overweight women

Public title

Assessment the effect of vitamin B6 supplementation on obesity and overweight

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Body mass index is over 25 kg / m² No changes in weight over 5 kg over the past 3 months No history of diabetes, cardiovascular, brain, kidney, liver, respiratory, digestive, thyroid Do not use drugs that affect lipid profile and blood glucose and contraception Not taking any supplements including antioxidants, minerals, omega 3 and B6 within 2 months before the start of the study Non-use of cigarettes and alcohol Non-Lactation and Not pregnancy

Exclusion criteria:

Lack of patient collaboration at each stage of intervention Pregnancy during intervention Identify any of the diseases or use the drugs mentioned in the criteria for entry Start a weight loss diet

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple (assigning a person to a particular group completely randomly) using a random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

The type of blindness in our study will be double-blind. Prior to the onset of the study, the box containing the

relevant pills are coded A and B by an individual except the researcher, in order to blind the researcher about which supplement each group received. When delivering supplements to patients, some one except the researcher should locate the patient in either A or B group by random number table. In this study, the patients and researcher (who collecting data, assessing the outcome and analyzing the data) should be kept blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahwaz University of Medical Sciences

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Golestan Highway

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Ahvaz

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Khuzestan

Postal code

61357-15794

Approval date

2018-10-23, 1397/08/01

Ethics committee reference number

IR.AJUMS.REC.1397.523

Health conditions studied**1****Description of health condition studied**

Obesity and overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Body composition

Timepoint

The beginning and end of the study

Method of measurement

Body Composition Analyser

2

Description

Visceral Fat

Timepoint

The beginning and end of the study

Method of measurement

Calculation

3

Description

Blood Glucose

Timepoint

The beginning and end of the study

Method of measurement

Blood test

4

Description

Plasma Insulin

Timepoint

The beginning and end of the study

Method of measurement

Blood test

5

Description

Insulin resistance

Timepoint

The beginning and end of the study

Method of measurement

Calculation

6

Description

Total Cholesterol

Timepoint

The beginning and end of the study

Method of measurement

Blood test

7

Description

Triglycerides

Timepoint

The beginning and end of the study

Method of measurement

Blood test

8

Description

HDL Cholesterol

Timepoint

The beginning and end of the study

Method of measurement

Blood test

9

Description

LDL Cholesterol

Timepoint

The beginning and end of the study

Method of measurement

Calculation

10

Description

leptin

Timepoint

The beginning and end of the study

Method of measurement

Blood test

11

Description

Adiponectin

Timepoint

The beginning and end of the study

Method of measurement

Blood test

Secondary outcomes

1

Description

Body Mass Index

Timepoint

The beginning and end of the study

Method of measurement

body weight / height square (kg/m²)

2

Description

Waist Circumference

Timepoint

The beginning and end of the study

Method of measurement

measurement

3

Description

Hip circumference

Timepoint

The beginning and end of the study

Method of measurement

measurement

Intervention groups

1

Description

Intervention group: pyridoxine hydrochloride Supplement, 2 pills 40 mg per day for 8 weeks

Category

Treatment - Drugs

2**Description**

Control group: Placebo, starch, 2 pills 40 mg per day for 8 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ahwaz University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz 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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Fateme Mirzaey

Position

Master of Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

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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