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

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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
Street address
Golestan Highway
City
Ahvaz
Province
Khouzestan
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 / hight square (kg/m2)

2

Description
Waist Circumference
Timepoint
The beginning and end of the study
Method of measurement
measurment

3

Description
Hip circumference
Timepoint
The beginning and end of the study
Method of measurement
measurment

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
Fateme Mirzaey
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Golestan Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mohammad Badavi
Street address
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badavi-m@ajums.ac.ir
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

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Person responsible for updating data

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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Province

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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