Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of high protein-weight loss diet combined with beta cryptoxanthin supplement on metabolic factors, serum levels of oxidants, inflammatory and adipocytokins among patients with nonalcoholic fatty liver disease.

Protocol summary

Summary

Nonalcoholic fatty liver disease (NAFLD) is one of the most common prevalent liver diseases, and associates with obesity, diabetes and insulin resistance (IR). Controversy exists regarding optimal macronutrient without energy restriction and beta – cryptoxanthin on NAFLD. The objective of this work is evaluation of the effect of high protein-weight loss diet combined with beta cryptoxanthin supplement on metabolic factors, serum levels of oxidants, inflammatory and adipocytokins among patients with nonalcoholic fatty liver disease. In this randomized, triple-blind, placebo-controlled clinical trial, ninety-two eligible patients, aged between 18–60 years, of both genders, alcohol consumption <20 g/day, serum ALT levels less than five times of the upper limit (maximum limit of 30 for women and 40 for men), lack of associated diseases and drugs with NAFLD will be randomly assign to 4 groups, label as Calorie restricted- high protein diet plus 6 mg beta cryptoxanthin (CR-HPD + β-CX) group, CR-HPD + placebo, Calorie restricted- normal protein diet plus 6mg beta cryptoxanthin (CR-NPD + β-CX) and CR-NPD + placebo (control group) for 3 months. Serum adiponectin and high sensitive-C-reactive protein (CRP) as primary outcomes will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060210181N10**
Registration date: **2017-06-20, 1396/03/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-20, 1396/03/30

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of high protein-weight loss diet combined with beta cryptoxanthin supplement on metabolic factors, serum levels of oxidants, inflammatory and adipocytokins among patients with nonalcoholic fatty liver disease.

Public title
Evaluation of the effect of high protein-weight loss diet combined with beta cryptoxanthin supplement on nonalcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria will be included: subjects will be overweight and obese (25≤BMI ≤40) individuals aged between 18–60 years of both genders, existence of NAFLD by ultrasound, NAFLD activity score less than 3, and willingness to participate. subjects with viral hepatitis, cirrhosis, Wilson's disease, acute fatty liver of pregnancy, hepatocellular carcinoma, hypothyroidism and a history of chronic liver disease, lipodystrophy, menopause, parenteral nutrition, bladder and bile duct disease, significant weight loss (≥10% of body weight during 6 months ago) or weight loss surgery, Congenital metabolic diseases, subjects on antioxidant supplementations, milk thistle and omega-3 fatty acids in the 6 months ago, a history of liver damaging drugs (amiodarone, anti-virus, aspirin, non-steroidal anti-inflammatories, corticosteroids, methotrexate, tamoxifen, tetracycline, valproic acid), alcohol consumption >20 g/day, calorie intake less than 800 kcal or more than 4200 a day, pregnancy and lactation, serum ALT levels more than five times of the upper limit (maximum limit of 30 for women and 40 for men), history of cardiovascular and kidney disease (urine analysis Albumina ≥ 30 (mg / 24 h) and GFR ≤ 90 ml / min / 1.73 m2) will be not included.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences
City
Ahvaz
Postal code
Approval date
2017-05-20, 1396/02/30
Ethics committee reference number
IR.AJUMS.REC.1396.138

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver disease
ICD-10 code
k75.8
ICD-10 code description
nonalcoholic steatohepatitis

Primary outcomes

1

Description
Plasma insulin
Timepoint
before intervention and after 3 months intervention
Method of measurement
colorimetry

2

Description
free fatty acids
Timepoint
before intervention and after 3 months intervention
Method of measurement
Eliza

3

Description
serum beta cryptoxanthin
Timepoint
before intervention and after 3 months intervention
Method of measurement
HPLC- C18

4

Description
serum adiponectin
Timepoint
before intervention and after 3 months intervention
Method of measurement
Eliza

5

Description
high sensitive-C-reactive protein (CRP)
Timepoint
before intervention and after 3 months intervention
Method of measurement
Eliza

Secondary outcomes

1

Description
weight
Timepoint
before intervention and after 3 months intervention
Method of measurement
electronic scale (Beurer PS160, Germany)

2

Description
BMI
Timepoint
before intervention and after 3 months intervention
Method of measurement
weight (kg)/height2 (m2)

3

Description
body fat mass
Timepoint
before intervention and after 3 months intervention
Method of measurement
Bioelectrical impendence analysis (BIA)

4

Description
LDL
Timepoint
before intervention and after 3 months intervention
Method of measurement
Enzymetic method

5

Description
HDL
Timepoint
before intervention and after 3 months intervention
Method of measurement
Enzymetic method

6

Description
Total cholesterol
Timepoint
before intervention and after 3 months intervention
Method of measurement
Enzymetic method

7

Description
triglyceride
Timepoint
before intervention and after 3 months intervention
Method of measurement
Enzymetic method

8

Description
fasting blood sugar
Timepoint
before intervention and after 3 months intervention
Method of measurement
Enzymetic method

9

Description
aspartate aminotransferase (AST)
Timepoint
before intervention and after 3 months intervention
Method of measurement
Enzymetic method

10

Description
alanine aminotransferase (ALT)
Timepoint
before intervention and after 3 months intervention
Method of measurement
Enzymetic method

11

Description
γ-glutamil transferase (GGT)
Timepoint
before intervention and after 3 months intervention
Method of measurement
Enzymetic method

12

Description
malondialdehyde (MDA)
Timepoint
before intervention and after 3 months intervention
Method of measurement
Satoh

13

Description
model-insulin resistance index (HOMA-IR)
Timepoint
before intervention and after 3 months intervention
Method of measurement
HOMA= fasting serum insulin (μU/ml)× fasting plasma

glucose (mM/L)/22.5

14

Description
HbA1c
Timepoint
before intervention and after 3 months intervention
Method of measurement
spectrophotometry

Intervention groups

1

Description
Intervention group1 : reduction of calorie intake by 500 K cal/day and diet with 30% fat, 25% protein, and 45% carbohydrates (high-protein diet) plus 6 mg beta crypthxanthin for 3 months
Category
Lifestyle

2

Description
Intervention group 2: reduction of calorie intake by 500 K cal/day and diet with 30% fat, 25% protein, and 45% carbohydrates (high-protein diet) plus placebo for 3 months
Category
Lifestyle

3

Description
Intervention group 3 : reduction of calorie intake by 500 K cal/day and diet with 30% fat, 15% protein, and 55% carbohydrates (normal protein diet) plus 6 mg beta cryptoxanthin for 3 months
Category
Lifestyle

4

Description
Control group : reduction of calorie intake by 500 K cal/day and diet with 30% fat, 15% protein, and 55% carbohydrates (normal protein diet) plus placebo for 3 months
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital of Ahvaz University
Full name of responsible person
Dr. Fatemeh Haidari
Street address
Ahvaz, Golestan hospital, Ahvaz Jundishapur University of Medical Sciences
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Behzad Sharif Makhmalzadeh
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Highway, ahvaz, iran Ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Dr. Fatemeh Heidari
Position
Associate Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty