

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effectiveness of Mediterranean and low fat diets compared with the regular pattern to improvement of symptoms in patients with knee osteoarthritis

Protocol summary

Study aim

- determination and compare of the effect of Mediterranean, low fat and conventional diet on weight in patients with knee osteoarthritis - determination and compare the effect of Mediterranean, low fat and conventional diet on WOMAC index in patients with knee osteoarthritis - determination and compare the effect of Mediterranean, low fat and conventional diet on VAS index in patients with knee osteoarthritis

Design

one-arm blinded parallel randomized clinical trial was done on 120 patients were categorized to Mediterranean, low fat and conventional diet for 3 month.

Settings and conduct

the present study is a one-arm blinded randomized feeding trial on 120 patients with grade 1-3 knee osteoarthritis (OA) at the Zanjan city with the mean age of 40-75 yrs. After written and informed consent, the initial assessments including sex, age, disease grade, as well as type of drugs will be asked and documented. Before the study enrollment, 3-days food diary record (two consecutive day and one holiday) will be filled for dietary intake assessment. Therefore, patients will be categorized to three groups. The total calorie will be considered as 28 kcal/kg. The third group will receive their conventional diet. At the Mediterranean diet, 35% of daily calorie will provide from fat, 15% from protein and 50% from carbohydrate. At the low fat diet, 20% of daily calorie will provide from fat, 15% from protein and 65% from carbohydrate. patient's compliance will be assessed by weekly call and 3-days food diary record.

Participants/Inclusion and exclusion criteria

patients with knee osteoarthritis according to the US rheumatologic association patients with grade 1-3 25<BMI<35 age of 49-75 yrs Iranian ethnicity

Intervention groups

Mediterranean diet low fat diet conventional diet

Main outcome variables

Weight WOMAC index VAS index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200929048876N1**

Registration date: **2020-10-01, 1399/07/10**

Registration timing: **prospective**

Last update: **2020-10-01, 1399/07/10**

Update count: **0**

Registration date

2020-10-01, 1399/07/10

Registrant information

Name

Seyedeh Neda Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3315 6300

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-05, 1399/07/14

Expected recruitment end date

2020-12-29, 1399/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of Mediterranean and low fat diets compared with the regular pattern of improvement of symptoms in patients with knee osteoarthritis

Public title
Useful Diet in patients with knee osteoarthritis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
knee osteoarthritis patients according to the US rheumatologic association criteria patients with grade 1-3 Body mass index between 25-35 Iranian ethnicity age of 40-75 yrs
Exclusion criteria:
history of joint replacement chronic disease such as inflammatory rheumatoid arthritis, cardiac, hepatic, kidney failure, cancer, acute myocardial infarct, type 1 and 2 diabetes mellitus, stroke, mental and nervous diseases and serious injuries injection or oral administration of corticosteroids for the past 6 month intake of alcohol and cigarette people who are on certain diets or have been on a diet for at the last 3 month people who don't follow the prescribed diets recent weight loss more than 4 kg during the last 2 month allergy and sensitivity to fish or impossibility of consuming it people who are undergoing physiotherapy or had physiotherapy to reduce pain over the past month opioid consumption or non-steroid anti-inflammatory drugs on a daily and continuous basis

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization will be used as three groups with 15-number blocks including 5 participant in each group. randomization unit is person and we will use random allocation software for this purpose. random coded boxes will be used for concealment. At this method, cans with similar weight, shape and color which are numbered according to the random sequence will be used.

Blinding (investigator's opinion)
Single blinded

Blinding description
Nutritionist and patients are aware of grouping. The outcome analyzer will be blinded and has no knowledge about grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanzan University of Medical Sciences

Street address

Azadi Blv

City

Zanzan

Province

Zanzan

Postal code

4513956184

Approval date

2020-01-17, 1398/10/27

Ethics committee reference number

IR.ZUMS.REC.1398.426

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

weight changes

Timepoint

baseline and after 3 month

Method of measurement

scale

2

Description

severity of pain alterations by WOMAC (Western Ontario and McMaster Universities Arthritis) index

Timepoint

baseline and after 3 month

Method of measurement

WOMAC questionnaire

3

Description

severity of pain alterations by Visual analog scale (VAS) index

Timepoint

baseline and after 3 month

Method of measurement

VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mediterranean diet which contains 35% of calorie from fats, 15% from protein and 50% from carbohydrates. This diet contains 27-37 gr fiber per day. After calorie counting and dividing the calories according to the above percent, the patients emphasis to receive at least half of their grain and bread from whole form. They can eat 1 time red meat (150 gr) at each month. Their daily oil consumption is olive oil (for salad) and canola oil (for frying).The main meat is white meat and receive 2 capsules of omega-3 each week. At least, one unit of legumes (half a glass of cooked beans) and nuts will be included in the daily diet. Dairy is as low fat and 6 glass of water will consume each day.

Category

Rehabilitation

2

Description

Intervention group: low fat diet which contains 20% of calorie from fats, 15% from protein and 65% from carbohydrates. In this dietary pattern, we will not have any specific recommendation for patients and only required dietary servings for each patient will be determined according the above percent and will be provided for each patient.

Category

Rehabilitation

3

Description

Control group: conventional group without any changes in dietary patterns of participants.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valie-Asr Haspital

Full name of responsible person

Dr. Alireza Sadeghi

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Shariati St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Zarrinjoie

Position

resident of internal medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Dr. Seyedeh Neda Mousavi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Zarrinjooie

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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

Zanjan University of Medical Sciences

Full name of responsible person**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

without participant name

When the data will become available and for how long

after study final

To whom data/document is available

all persons

Under which criteria data/document could be used

all persons

From where data/document is obtainable

Zanjan University of Medical Sciences, Deputy of Research and Technology

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

straight referee to Deputy of Research and Technology of Zanjan University of Medical Sciences

Comments