

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Assessment of the effects of Mediterranean and low fat diets compared with regular diet on improvement of symptoms in patients with rheumatoid arthritis

Protocol summary

Study aim

- determination and compare of the effect of Mediterranean, low fat and conventional diet on weight and pain severity in patients with rheumatoid arthritis (RA).

Design

one-arm blinded parallel randomized clinical trial was done on 168 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 168 patients with rheumatoid arthritis (according to the American Rheumatologic association) at the Zanjan city with the mean age of 15-75 yrs. Before the study enrollment, 3-days food diary record will be filled for dietary intake assessment. The total calorie will be considered as 28 kcal/kg. 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.

Participants/Inclusion and exclusion criteria

inclusion criteria Rheumatoid patients according to the US rheumatologic association criteria rheumatoid patients at the activated phase of disease, body mass index between 25-35, age of 15-75 yrs, Iranian ethnicity exclusion criteria pregnant or lactating women or who decided to pregnant, intake of multivitamins or minerals supplements at least at the last 3 month 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 opioid consumption or non-steroid anti-inflammatory drugs on a daily and continuous basis, intake of alcohol and cigarette, maldigesting diseases such as celiac and steatorrhea

Intervention groups

Mediterranean diet low fat diet conventional diet

Main outcome variables

Weight, DAS28 index, VAS index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200929048876N2**

Registration date: **2020-10-09, 1399/07/18**

Registration timing: **retrospective**

Last update: **2020-10-09, 1399/07/18**

Update count: **0**

Registration date

2020-10-09, 1399/07/18

Registrant information

Name

Seyedeh Neda Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3315 6300

Email address

neda.mousavi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-19, 1398/11/30

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

2020-02-19, 1398/11/30
Actual recruitment end date
 2020-07-20, 1399/04/30
Trial completion date
 2020-09-20, 1399/06/30

Scientific title
 Assessment of the effects of Mediterranean and low fat diets compared with regular diet on improvement of symptoms in patients with rheumatoid arthritis

Public title
 Useful Diet in patients with rheumatoid arthritis

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Rheumatoid patients according to the US rheumatologic association criteria rheumatoid patients at the activated phase of disease body mass index between 25-35 age of 15-75 yrs Iranian ethnicity
Exclusion criteria:
 pregnant or lactating women or who decided to pregnant intake of multivitamins or minerals supplements at least at the last 3 month 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 opioid consumption or non-steroid anti-inflammatory drugs on a daily and continuous basis patients at the remission phase of disease other chronic diseases except of rheumatoid arthritis intake of alcohol and cigarette maldigesting diseases such as celiac and steatorrhea

Age
 From **15 years** old to **75 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **168**
 Actual sample size reached: **168**

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

Ethic committee of Zanjan University of Medical Sciences

Street address

Azadi Blv

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2020-01-16, 1398/10/26

Ethics committee reference number

IR.ZUMS.REC.1398.425

Health conditions studied

1

Description of health condition studied

rheumatoid arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Weight changes

Timepoint

baseline and after 3month

Method of measurement

scale

2

Description

pain severity

Timepoint

baseline and after 3 month

Method of measurement

VAS and DAS28 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 Hospital

Full name of responsible person

Dr. Alireza Sadeghi

Street address

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. Mojtaba Tabatabaiee Befroodi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

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 Thechnology

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