Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Sep 2026

Investigating the effects of MCT-modified ketogenic diet on clinical symptoms, systemic inflammation and the expression of gene coding B-catenin in patients with endometriosis: A parallel randomized clinical trial

Protocol summary

Study aim

To determine the effect of ketogenic diet modified with MCT oil on clinical symptoms, systemic inflammation, and expression of gene coding B-catenin protein in patients with endometriosis

Design

A controlled, parallel-group, randomized, phase 2-3 clinical trial on 50 patients. Randomization is done by permuted block randomization method using blocks of 4 and based on the severity of endometriosis

Settings and conduct

This study will be conducted on women with newly diagnosed endometriosis referred to the infertility clinic of Yas Hospital. First, eligible patients enter a two-week run-in period. Then they will be randomly assigned to one of the groups of the standard medication regimen (oral contraceptive pill) and the ketogenic diet modified with MCT oil or the control group (standard medication regimen(oral contraceptive pill)). The duration of intervention for both groups is 12 weeks.

Participants/Inclusion and exclusion criteria

Married women with stage one or two endometriosis whose body mass index is between 21 and 25 kg/m2 can enter the study. Also, these patients should not be pregnant, lactating, or postmenopausal, and should not have a myoma or polyps in the uterus and history of kidney, liver, and cardiovascular disease, or diabetes.

Intervention groups

For the people in the intervention group, standard drug regimen (oral contraceptive pill) and ketogenic diet are considered. For the control group, the standard drug regimen (oral contraceptive pill) is considered.

Main outcome variables

Changes in the expression of the gene coding B-catenin protein and changes in the score of clinical symptoms are considered as the primary outcomes and changes in anthropometric measurements, systemic inflammation indices, lipid profile, liver enzymes, and systolic and diastolic blood pressure are considered as secondary outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131125015536N15**
Registration date: **2024-07-24, 1403/05/03**
Registration timing: **prospective**

Last update: **2024-07-24, 1403/05/03**
Update count: **0**

Registration date

2024-07-24, 1403/05/03

Registrant information

Name

Mohammad Javad Hosseinzadeh

Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-20, 1403/08/30

Expected recruitment end date

2025-06-20, 1404/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of MCT-modified ketogenic diet on clinical symptoms, systemic inflammation and the expression of gene coding B-catenin in patients with endometriosis: A parallel randomized clinical trial

Public title

Effects of ketogenic diet in patients with endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range between 25 and 35 years being married Diagnosis of endometriosis based on laparoscopic and pathological findings Having stage one or two endometriosis based on diagnostic laparoscopy or patients with a higher grade who underwent diagnostic-therapeutic laparoscopy and 3 months after laparoscopy, their disease stage was reduced to stage one or two Body mass index between 21 and 25 kg/m2 Having a VAS score of 3 out of 10 or greater than 3 out of 10 for pelvic pain and dyspareunia (pain during intercourse) and dyschezia (pain during defecation)

Exclusion criteria:

Smoking and alcohol consumption Taking antidepressants for the past 6 months Pregnancy, breastfeeding and menopause Women who intend to become pregnant or take drugs such as clomifene, letrozole and gonadotropin Intestinal malabsorption (history of bariatric surgery, inflammatory bowel disease, celiac disease) Suffering from other diseases such as kidney disease and kidney stones, liver disorders and gallstones, cancer, heart diseases, acute and chronic infectious diseases, type 1 and 2 diabetes, Cushing's disease, acromegaly, and gigantism. Having myoma or polyps in the uterus

Age

From **25 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done by the Permuted Block Randomization method at the end of the Run-in period. In this method, eligible people who meet the criteria for entering the study are selected and then randomly assigned using 4 blocks based on the severity of endometriosis disease (first stage and second stage) in a random allocation method. They will be assigned to one of the two ketogenic and control diet groups. In random allocation, based on the list of random numbers, the letters A and B are assigned to the number equal to the random numbers. In this way, the letters A and B will be spread between the patient codes. Numbers will be assigned to patients according to the order of participants' entry, and patients will receive standard medical treatment (oral contraceptive pill) and ketogenic diet or standard medical treatment (oral contraceptive pill) based on specific letters (A and B).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of school of medicine-Tehran university of medical sciences

Street address

Keshavarz Blvd

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Province

Tehran

Postal code

1416643931

Approval date

2024-07-12, 1403/04/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.167

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80.0

ICD-10 code description

Endometriosis of uterus

Primary outcomes

1

Description

Expression of the gene coding beta-catenin protein

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (3 months after the intervention)

Method of measurement

RT-PCR method

2

Description

Score of clinical symptoms including pelvic pain, dyspareunia, and dyschezia

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (3 months after the intervention)

Method of measurement

visual analog scale

Secondary outcomes

1

Description

Anthropometric measurements including weight, body mass index, waist circumference

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (3 months after the start of the intervention)

Method of measurement

By a trained person using a scale and tape measure and calculating body mass index using the formula

2

Description

Systemic inflammation indices including neutrophil-to-lymphocyte ratio, monocyte-to-lymphocyte ratio, platelet-to-lymphocyte ratio, and systemic inflammation response index

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (3 months after the start of the intervention)

Method of measurement

Using the formula and data from the complete blood cell count test

3

Description

Lipid profile including total cholesterol (TC), triglyceride (TG), high-density lipoprotein (HDL-C) and low-density lipoprotein (LDL-C)

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (3 months after the start of the intervention)

Method of measurement

Photometric method using laboratory kits

4

Description

Liver enzymes (ALT and AST)

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (3 months after the start of the intervention)

Method of measurement

Enzymatic method using laboratory kits

5

Description

Systolic and diastolic blood pressure

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (3 months after the start of the intervention)

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Intervention group: In addition to the prescription of the standard drug regimen, i.e., oral contraceptive pills, the intervention of the ketogenic diet is explained to the patients of this group, and each patient is consulted by a nutritionist, and a ketogenic diet modified with MCT oil is written for them. Calories The diet is calculated based on the Meflin formula and based on the current weight. The designed diet consists of 70-80% fat, 15-20% protein, and 5-10% carbohydrates. The ratio of grams of fat and protein to carbohydrates is 3:1, and along with the diet, 500 cc of MCT oil was given to the patients every three weeks to accelerate the process of ketosis. Since MCT oil is tasteless, patients are advised to take 8 cc of oil (based on the amount written in the diet) after a main meal with a salad or on its own. About 40 food menus are written for patients to use any menu they like based on their personal preferences for 12 weeks.

Category

Treatment - Other

2

Description

Control group: Patients will be given a standard drug regimen (oral contraceptive pill) for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital Complex

Full name of responsible person

Fatemeh Naeini

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Javad Hosseinzadeh Attar

Position
Professor

Latest degree
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Other areas of specialty/work
Nutrition

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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable