Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Pilot evaluation of the anti-inflamation and analgesics effect of oral administration of Melissa officinalis in patients with Rheumatoid arthritis: a double-blind randomized crossover trial

Protocol summary

Study aim

Evaluation of the anti-inflammation and analgesics effect of Melissa officinalis in patients with moderate Rheumatoid arthritis and evaluation of inflammatory factors and cytokines

Design

Randomized Double-Blind, Placebo-Controlled Clinical Trial, parallel, Drug and Placebo, Phase 2 on 20 patients with moderate rheumatoid arthritis using computere randomization method.

Settings and conduct

This study was conducted on 20 ژutpatients referring to Rheumatology Clinic, Imam Khomeini Hospital Complex. Patients are classified into intervention groups after being informed about the study and obtaining informed consent. Medicines have no name and only numbers and are given to the patient. Tests and examinations are performed and compared before and after the intervention. Researchers, rheumatologists, and patients are unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient satisfaction and signing of the informed consent form, Confirmation of patients with moderate Rheumatoid Arthritis Using the Criteria of the American College of Rheumatology, Patients over 18 years, During the period of the disease up to 15 years, DAS Score between 3-5 Exclusion Criteria: Lack of cooperation of patientsو History of Heart, kidney, liver and ... diseasesو Pregnancyو Any kind of Immunodeficiency diseasesو No other autoimmune diseases

Intervention groups

Drug Group: Capsule containing Melissa officinalis dry leaf, 500 mg Placebo: Capsule containing Bread powder, 500 mg

Main outcome variables

Level measurement of inflammatory factors ESR, CRP, RF, CBC, Evaluation of inflammatory cytokines TNF-α, IL-17 in serum, calculation of DAS28 and VAS Score in rheumatoid arthritis patients to assess pain and inflammation level, Evaluation of WHOQOL quality of life questionnaires and Beck Depression 2 before and after treatment, and Anti ccp test before treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201126049498N1**
Registration date: **2021-03-10, 1399/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-10, 1399/12/20**
Update count: **0**

Registration date

2021-03-10, 1399/12/20

Registrant information

Name

Abdolrahman Rostamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 1294

Email address

ar.rostamian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-06, 1399/12/16

Expected recruitment end date

2021-08-07, 1400/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pilot evaluation of the anti-inflamation and analgesics effect of oral administration of Melissa officinalis in patients with Rheumatoid arthritis: a double-blind randomized crossover trial

Public title

effect of Melissa officinalis in treatment of patient with Rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient satisfaction and signing of informed consent form Diagnosis of patients with moderate Rheumatoid Arthritis Using the Criteria of the American College of Rheumatology Patients over 18 years During the period of the disease up to 15 years DAS Score between 3-5

Exclusion criteria:

Lack of cooperation of patients History of Heart, kidney, liver and ... diseases Pregnancy Any kind of Immunodeficiency diseases No other autoimmune diseases

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Sampling before and after treatment

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we used Random Allocation software for randomization. The random sequence of samples was performed equally as Intervention and Placbo groups using this software. For allocation concealment, sealed envelopes were used. In this method, each of the random sequences written on a card and they is placed in the envelopes, respectively. Finally, the lid of the envelopes is glued and placed in a box, respectively. At the registration time, based on the order in which eligible participants enter the study, one of the envelopes of their choice will be opened and their assigned group will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Bottles of drugs and placebo were coded by an expert one in the research center. Researchers, patients, data collectors, and evaluators assess the outcome, are not aware of the contents of the package and grouping, and samples were delivered as random double-blind to the patient. Patients received the number to their referral and entered the study. The number of patients was randomly selected by computer and divided into two groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahed University Committee for Ethics in biomedical Research

Street address

Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway

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Tehran

Province

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Postal code

3319118651

Approval date

2018-10-29, 1397/08/07

Ethics committee reference number

IR.SHAHED.REC.1397.073

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis disease

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Evaluation of Disease Activity Score 28 (DAS 28)

Timepoint

2 months after and before treatment

Method of measurement

DAS Calculator software

2

Description

Evaluation of ESR (Erythrocyte Sedimentation Rate

Timepoint

2 months after and before treatment

Method of measurement

Using Westergren method

3

Description

Evaluation of Rheumatoid Factor (RF)

Timepoint

2 months after and before treatment

Method of measurement

Quantitative method with diagnostic kit

4

Description

Evaluation of CRP (C-Reactive Protein)

Timepoint

2 months after and before treatment

Method of measurement

Quantitative method with diagnostic kit

5

Description

Evaluation of Anti ccp (Cyclic Citrirullinated Peptide)

Timepoint

Before treatment

Method of measurement

ELISA method

6

Description

Assay of TNF-α (Tumor necrosis factor α)

Timepoint

2 months after and before treatment

Method of measurement

ELISA method

7

Description

Assay of Interleukin 17 (IL-17)

Timepoint

2 months after and before treatment

Method of measurement

ELISA method

8

Description

Evaluation of visual analog scale (VAS)

Timepoint

2 months after and before treatment

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Evaluation of World Health Organization Quality of Life-BREF (WHOQOL-BREF)

Timepoint

2 months after and before treatment

Method of measurement

Questionnaire

2

Description

Evaluation of Beck Depression Inventory (BDI-II)

Timepoint

2 months after and before treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Melissa officinalis is a perennial herbaceous plant in the mint family (Lamiaceae). Scientific research of this plant shows that it has anti-inflammatory, analgesic, and anti-depressant effects. Dried M. officinalis leaves after powdering in the mill, were administered to patients as 500 mg capsules twice a day (once every 12 hours) for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Ready bread crumbs without any additives, were administered to patients as 500 mg capsules twice a day (once every 12 hours) for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Clinic, Imam Khomeini hospital, Tehran

Full name of responsible person

Abdolrahman Rostamian

Street address

Imam Khomeini Hospital Complex, Qarib Avenue, the end of Keshavarz Boulevard

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
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naseri@shahed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University
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
Shahed University
Full name of responsible person
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Email

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All impersonal data of the participants without any name; Information on the main implications and all the information obtained from the research were published in article.

When the data will become available and for how long

In the relevant article after its publication

To whom data/document is available

Everyone who has access to the published article

Under which criteria data/document could be used

After publication in the journal

From where data/document is obtainable

Article and Dr Azadeh Mizani as the main researcher azadeh.mizani@yahoo.com

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

An email to that person

Comments