Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluate the health benefits of the BTMC-1 drug product in rheumatoid arthritis patients: a double-blinded randomized clinical trial

Protocol summary

Study aim

Determining the effect of BTMC-1 medicinal product on the serum levels of RF and antiCCP, the serum levels of pro-inflammatory cytokines (IL6, TNFα and IL1), the number of white blood cells, CRP and ESR levels, pain, disease severity, morning joint stiffness duration, the number of tender and swollen joints, the disability of RA patients

Design

A randomized,double-blinded,controlled phase 2 clinical trialwith factorial groups on 40 patients. Randomization will be done based on the permutation of random blocks.

Settings and conduct

Sample collection will be done in Imam Khomeini Hospital and they will be introduced to the laboratory. Sampling and completing the questionnaires will be done two times (before and after the intervention). The intervention and placebo will have the same appearance, and the doctor and patients will be blinded.

Participants/Inclusion and exclusion criteria

Informed consent of the patient, confirmation of rheumatoid arthritis criteria , between 20 to 65 years old, female, with active rheumatoid arthritis (DAS28 between 2.6 and 5.1) , constant treatment before and during the intervention, the duration of the disease should be less than 5 years, using methotrexate as the main treatment;Lack of consent to continue participating ,Suffering from another disease, consumption of any vitamins, minerals and nutritional supplements, patients with DAS28˃5.1, pregnancy and lactation, being relatives of patients, irregular consumption of the intervention, excessive consumption of fruit and natural fruit juices during the intervention

Intervention groups

Intervention: BTMC-1 (800 mg of matricaria chamomile hydroalcoholic extract per capsule), two capsules will be consumed daily for 45 days .control group will receive caspules which just have basic ingrediants.

Main outcome variables

Pro-inflammatory cytokines, RF and anticcp ,pain, disease severity and disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230209057368N1**
Registration date: **2023-02-20, 1401/12/01**
Registration timing: **prospective**

Last update: **2023-02-20, 1401/12/01**
Update count: **0**

Registration date

2023-02-20, 1401/12/01

Registrant information

Name

Mahdiyeh Nateghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6641 8216

Email address

nateghimahdiyeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-24, 1401/12/05

Expected recruitment end date

2024-02-24, 1402/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluate the health benefits of the BTMC-1 drug product in rheumatoid arthritis patients: a double-blinded randomized clinical trial

Public title
Evaluate the health benefits of the BTMC-1 drug product in rheumatoid arthritis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent of the patient to participate in the study and sampling Confirmation the criteria of rheumatoid arthritis disease by the attending physician and laboratory findings patients who have active rheumatoid arthritis (2.6<DAS28<5.1) Patients should have fixed treatment 3 weeks before the intervention and during the intervention The duration of the disease in patients should be less than 5 years Consume the methotrexate as the main treatment

Exclusion criteria:
Lack of consent to continue participating in the study Having another disease that requires active medical care Consumption of any vitamins, minerals and food supplements 3 months before the intervention and during the intervention (except vitamin D which is consumed by all patients) Patients who have DAS28 higher than 5.1 Pregnancy and lactation Patients who are relatives in order to avoid statistical bias Irregular consumption of intervention Excessive consumption of fruit and natural fruit juices during the intervention

Age
From **20 years** old to **65 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
10 ml of peripheral blood per session

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization will be done based on the permutation of random blocks, in such a way that the drug and placebo are specified as, A and B, and the random numbers generated by the RAND function in Excel software are dedicated to the AB and BA blocks (binary block) and finally, based on random numbers, the list of drug and placebo will be assigned for patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention and the placebo will have the same appearance, and neither the doctor nor the patient will be in the process of taking the intervention or the placebo

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahed University

Street address
Shahed University, in front of the Holy Shrine of Imam Khomeini, in the beginning of Tehran-Qom highway ,Tehran

City
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Province
Tehran

Postal code
3319118651

Approval date
2023-01-30, 1401/11/10

Ethics committee reference number
IR.SHAHED.REC.1401.146

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis

ICD-10 code
M05

ICD-10 code description
Seropositive rheumatoid arthritis

Primary outcomes

1

Description
The amount of pro-inflammatory cytokines(interleukin 6,1,TNF-alpha)

Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption

Method of measurement
Sandwich ELISA (ELISA Kit, R&D System Company)

2

Description
the amount of rheumatoid factor autoantibody
Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption
Method of measurement
Turbidometry with Hitachi 912 device

3

Description
The amount of Anti-cyclic citrullinated peptide (anti-CCP) antibody
Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption
Method of measurement
ELISA (ELISA Kit, R&D System Company)

4

Description
Erythrocyte sedimentation rate
Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption
Method of measurement
Westergren-Katz tube

5

Description
C-reactive protein
Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption
Method of measurement
Hitachi autoanalyzer

6

Description
White blood cells count
Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption
Method of measurement
hematologic autoanalyzer(sysmex)

Secondary outcomes

1

Description
the amount of pain
Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption
Method of measurement
Visual Analogue Scale

2

Description
severity of the disease
Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption
Method of measurement
disease activity questionnaire 28 (DAS28)

3

Description
the duration of morning joints stiffness
Timepoint
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption
Method of measurement
Patient self-report in minutes

4

Description
evaluation of the disability
Timepoint
health assessment questionnaire - disability index(HAQ-DI)
Method of measurement
At the beginning of the study and 45 days after the intervention (pharmaceutical product BTMC-1) consumption

Intervention groups

1

Description
Intervention group:medicinal product BTMC-1 (capsule prepared from hydroalcoholic extract of Matricaria chamomile), each capsule contains 800 mg of hydroalcoholic extract of Matricaria chamomile, patients will take two capsules daily with food, the duration of the intervention is 45 days. BTMC-1 medicinal product is edible, this capsule is prepared and produced by Behpad Teb Iranian Company.
Category
Treatment - Drugs

2

Description
Control group: Capsules containing basic ingredients without matricaria chamomile hydroalcoholic extract
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person
Seyed Reza Najafizadeh

Street address
Department of Rheumatology, fifth floor of Valiasr building,Imam khomeini hospital, Dr.gharib Ave, Kheshavarz Blvd, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Immunoregulation Research Center

Full name of responsible person
Tooba Ghazanfari

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No.1471, Shahed University Research Center Complex, Immunoregulation Research Center, Karghar Shomali St, before Nosrat St

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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
Immunoregulation Research Center

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
Mahdiyeh Nateghi

Position
Master`s student

Latest degree
Bachelor

Other areas of specialty/work
Immunology

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Person responsible for updating data

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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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Since it is mentioned that the information remains confidential, it is possible to publish this data file only if it is coded and without inserting the patients' information.

When the data will become available and for how long
the data will be accessible by 2025

To whom data/document is available
The data will be available to people working in scientific and academic centers and institutions

Under which criteria data/document could be used
Individuals will only be allowed to use data to ensure accuracy and verification or to achieve sample size in their studies.

From where data/document is obtainable
email: natighimahdiyeh@yahoo.com

What processes are involved for a request to access data/document
After meeting the mentioned conditions and confirming it by the responsible person, the data will be available within one working week.

Comments