

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of quercetin on inflammatory cytokines and clinical signs of patient with human T-cell lymphotropic virus type 1-associated myelopathy/tropical spastic paraparesis (HAM/TSP): The randomized clinical trial

Protocol summary

Study aim

The assessment of quercetin drug on inflammatory cytokines and clinical signs of patients with human T-cell lymphotropic virus type 1-associated myelopathy/tropical spastic paraparesis (HAM/TSP)

Design

Randomized clinical trial of placebo group, with parallel groups, double-blind, phase 3 on 40 patients. The www.sealedenvelope.com was used to generate a blocked random allocation sequence.

Settings and conduct

In this randomized clinical trial study, patients with tropical spastic myelopathy/paraparesis caused by human type 1 lymphotropic T virus (HAM / TSP) referred to Ghaem Hospital in Mashhad are randomly assigned to one of the two intervention or placebo groups after obtaining informed consent. Double-blind randomization will be done by packets in the package. Based on a pre-designed checklist, patients in both groups will be evaluated for 12 weeks, with clinical signs, interferon-gamma, TNF- α , and IL-4 cytokine levels, as well as virus loading at the baseline (day 1), and the end-point (end of 12 weeks).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with human T-cell lymphotropic virus type 1 (HTLV-1)-associated myelopathy/tropical spastic paraparesis (HAM/TSP) Conscious consent to participate in the study Aged 18 years and older Exclusion criteria: Pregnancy and lactation Diagnosis of blood diseases and blood cancers such as leukemia Dissatisfaction with participating in the study

Intervention groups

In the intervention group, patients take one quercetin 500 mg capsule daily for 12 weeks in addition to routine treatment (taking gabapentin).

Main outcome variables

Interferon-gamma cytokine level, TNF- α cytokine level, IL-4 cytokine level and viral load, as well as patients' clinical symptoms such as lower extremity weakness and urinary disorders at the beginning (first day) and end of follow-up (end of 12 weeks)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210531051459N2**

Registration date: **2022-04-08, 1401/01/19**

Registration timing: **prospective**

Last update: **2022-04-08, 1401/01/19**

Update count: **0**

Registration date

2022-04-08, 1401/01/19

Registrant information

Name

Mona Kabiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

kabirimn@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of quercetin on inflammatory cytokines and clinical signs of patient with human T-cell lymphotropic virus type 1-associated myelopathy/tropical spastic paraparesis (HAM/TSP): The randomized clinical trial

Public title
The assessment of quercetin in patients with human T-cell lymphotropic virus type 1-associated myelopathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with human T-cell lymphotropic virus type 1 (HTLV-1)-associated myelopathy/tropical spastic paraparesis (HAM/TSP) Conscious consent to participate in the study Aged 18 years and older
Exclusion criteria:
Pregnancy and lactation Diagnosis of blood diseases and blood cancers such as leukemia Consumption of quercetin in the last three months Crocin supplementation Curcumin supplementation Vitamin C supplementation Dissatisfaction with participating in the study

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization type: Block Randomization unit: Individual Randomization tool: www.sealedenvelope.com
How to create a random sequence: At www.sealedenvelope.com, the randomization section, after selecting the list, specifies the number of groups, the size of the blocks (4, 8, 10, 16) and the length of the list, and provides the list accordingly. Allocation Concealment: Sealed envelopes Participants are given an envelope according to which they are placed in one of two groups.

Blinding (investigator's opinion)

Double blinded
Blinding description
In this study, participants did not know the type of treatment they received. Also, patient clinicians, physicians, and outcome assessors are unaware of how patients are grouped and use medication or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghaem Hospital, Ahmad Abad Ave., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91766-99199

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.817

Health conditions studied

1

Description of health condition studied

Human T-cell lymphotropic virus associated myelopathy

ICD-10 code

G04.1

ICD-10 code description

Human T-cell lymphotropic virus associated myelopathy

Primary outcomes

1

Description

The level of Interferon-gamma cytokine

Timepoint

Beginning of the study and the end of 12 weeks

Method of measurement

Blood sampling and serum isolation

2

Description

The level of TNF- α cytokine

Timepoint

Beginning of the study and the end of 12 weeks

Method of measurement

Blood sampling and serum isolation

3

Description

The level of Interleukin-4 cytokine

Timepoint

Beginning of the study and the end of 12 weeks

Method of measurement

Blood sampling and serum isolation

Secondary outcomes

1

Description

Virus load rate

Timepoint

Beginning of the study and the end of 12 weeks

Method of measurement

Blood sampling and DNA extraction

2

Description

The rate of urinary disorders by urinary disturbance score (UDS)

Timepoint

Beginning of the study and the end of 12 weeks

Method of measurement

Use of the Urinary Disturbance Score (UDS): This scale is the sum of 3 sub-scales, each of which measures the severity of the urinary symptom such as recurrence, incomplete bowel movements, and urinary incontinence. In each subscale, the minimum score is zero (normal) and the maximum score is 4 (severe), that is measured by a neurologist based on the patient's history.

3

Description

Spasticity intensity by Ashworth scale

Timepoint

Beginning of the study and the end of 12 weeks

Method of measurement

Use of Ashworth scale: The severity of spasticity is scored with a minimum of zero (lack of spasticity) and a maximum of 4 (limb stiffness in both flexion and extension) based on the patient history and clinical examination by a neurologist.

4

Description

Severity of movement disorder by Osama Motor Disability Scale

Timepoint

Beginning of the study and the end of 12 weeks

Method of measurement

Osama Motor Disability Scale: The severity of movement disorder is scored with a minimum of zero (normal) and a maximum of 13 (bedbound), based on the patient history and clinical examination by a neurologist.

5

Description

Severity of movement disorder by Motor Disability Grading

Timepoint

Beginning of the study and the end of 12 weeks

Method of measurement

Motor Disability Grading Scale: The severity of movement disorder is scored with a minimum of zero (normal) and a maximum of 10 (bedbound). This scale is a modification of the Osama scale, which is graded based on a patient history and clinical examination by a neurologist.

Intervention groups

1

Description

Intervention group: The enrolled patients take one 500 mg quercetin capsule daily for 12 weeks, in addition to routine treatment (gabapentin).

Category

Treatment - Drugs

2

Description

Control group: The enrolled patients take one placebo capsule daily for 12 weeks in addition to routine treatment (gabapentin). The placebo capsule contains starch and is similar in appearance, weight and packaging to quercetin capsules.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Mona Kabiri

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Ghaem hospital, Ahmad Abad Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Vice Chancellor for Research and Technology,
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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mona Kabiri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Nanotechnology

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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

No - There is not 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

Potential data can be shared after participants are not identified.

When the data will become available and for how long

Access period will be started 9 months after the published results.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The use of data and its analysis is allowed by mentioning the source.

From where data/document is obtainable

It is necessary to send an email to the corresponding author of the article for receiving the data.

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

The processes that a researcher who requests data goes through will include a letter of request from the person, a letter of request from the center or university of origin, and acceptance of the destination university to receive the information.

Comments