Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Teriflunomide’s safety and effect on clinical signs, inflammatory and viral factors in patients with HTLV-1-induced myelopathy

Protocol summary

Study aim
Evaluating the safety and therapeutic effects of Teriflunomide on clinical symptoms, inflammatory and viral factors in patients with HTLV-1-induced myelopathy

Design
A phase 3, triple-blinded, controlled clinical trial with two parallel group desgin of 22 patients in a single center

Settings and conduct
The study will be performed at the Department of Neurology at Ghaem Hospital in Mashhad. Patients will be blinded with placebo and outcome assessors and data analyser will be unaware of study groups.(HTLV-1 Clinic)

Participants/Inclusion and exclusion criteria
Inclusion criteria are patient with HAM/TSP with moto disability under MDG score of nine. Exclusion criteria are patient with other autoimmune disorders comorbidity and patient under treatment with immunosuppressive drugs.

Intervention groups
Intervention group: Oral administration of one 14-mg Teriflunomide tablet daily for 12 months Control group: Oral administration placebo (the same tablet regarding colour and shape compared to the intervention group) for 12 months

Main outcome variables
Serum levels of TNF-a, NFL; Viral load levels; The measures of MRC (muscle strength); Ashworth (spasticity); OMDS (motor disability); UDS (urinary tract disorder);

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180618040127N3**
Registration date: **2021-11-19, 1400/08/28**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-19, 1400/08/28**
Update count: **0**

Registration date
2021-11-19, 1400/08/28

Registrant information

Name
Zohreh Vahidi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-06, 1400/04/15

Expected recruitment end date
2022-07-06, 1401/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Teriflunomide’s safety and effect on clinical signs, inflammatory and viral factors in patients with HTLV-1-induced myelopathy

Public title
The safety and effect of Teriflunomide in patients with

HTLV-1-induced myelopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive serology for Human T-cell Lymphotropic Virus Type-1 (HTLV-1) Occurrence of spastic paraparesia Existence of anti HTLV-1 antibody in cerebrospinal fluid Rule out of other etiologies of spastic paraparesia Motor Disability Grading (MDG) less than 9 Informed consent for participating in the study

Exclusion criteria:

Existence of other active and latent infections include of old or active tuberculosis or hepatitis Receiving other drug which influence immune system Severe renal dysfunction Married women of childbearing age who do not use safe contraception

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Depending on the time of arrival of patients in the study, the patient randomly selects one of the letters of the English alphabet from A to V. These letters are defined as placebo and main drug in the pre-prepared tables with the main analyzer. In addition, the order of English letters and medicines has been randomly drawn by the main analyzer. we have 22 patients that divided into two groups(ie, pill drug and placebo) thus we select 22 English alphabetic words (ie, A to V) witch 11 words belong to cases and 11 words belong to control. we write the name case or control on the paper and put on of them into an open box and 22 patients incidentally pick of them and they don't see the result and they give that paper to us.

Blinding (investigator's opinion)

Triple blinded

Blinding description

According to the explanations given in the way of randomization and with the coordination of the drug manufacturer, the coating and packaging form of the placebo and the drug are considered the same and are coded as A to V and delivered to the main analyzer. At the end of the study, these letters of the alphabet a to v are decoded.

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

Opposite Daneshgah 18, Daneshgah Avenue, Central bulding of Mashhad University of Medical Sciences (Ghoreishi)

City

Mashhad

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Razavi Khorasan

Postal code

9138813944

Approval date

2020-07-21, 1399/04/31

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.441

Health conditions studied

1

Description of health condition studied

HTLV-1 associated myelopathy/tropical spastic paraparesis (HAM/TSP) patients

ICD-10 code

G04.1

ICD-10 code description

Tropical spastic paraplegia

Primary outcomes

1

Description

Serum level of inflammatory cytokines (TNF-a and NFL) and Viral load

Timepoint

At the begging of study and 12 months later

Method of measurement

Serum level evaluation

Secondary outcomes

1

Description

Medical Research Council (MRC) Scale for Muscle Strength

Timepoint

At the begging of study and months of three, six, nine and twelve

Method of measurement

Physical examination

2

Description

Spasticity score with Ashworth scale

Timepoint

At the begging of study and months of three, six, nine and twelve

Method of measurement

Physical examination

3

Description

Motor Disability score with Osame Motor Disability Score

Timepoint

At the begging of study and months of three, six, nine and twelve

Method of measurement

Physical examination

4

Description

Urinary disturbance score

Timepoint

At the begging of study and months of three, six, nine and twelve

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: Daily administration of one 14-mg tablets of Teriflunomide for 12 months. The drug company is Dr. Abidi.

Category

Treatment - Drugs

2

Description

Control group: Daily administration of one placebo (tablet in same color and shape with intervention group) for 12 months. The placebo company is Dr. Abidi.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem Hospital

Full name of responsible person

Dr. MohammadAli Nahayati

Street address

Ahmad abad Street, before Shariati Square. Qaem Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Dr. MohammadAli Nahayati
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
I haven't decided yet - the release schedule is still unknown
When the data will become available and for how long
I haven't decided yet - the release schedule is still unknown
To whom data/document is available
I haven't decided yet - the release schedule is still unknown
Under which criteria data/document could be used
I haven't decided yet - the release schedule is still unknown
From where data/document is obtainable
I haven't decided yet - the release schedule is still unknown
What processes are involved for a request to access data/document
I haven't decided yet - the release schedule is still unknown
Comments