

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effect of Dalfampridine on dysfunction of walking in patients with HTLV-1-induced myelopathy

Protocol summary

Study aim

Evaluating the therapeutic effects of Dalfampridine on the gait disorders in patients with HTLV-1-induced myelopathy

Design

A phase 3, triple-blinded, controlled clinical trial with two parallel-group designs of 40 patients

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 analyzers will be unaware of the study groups.(HTLV-1 Clinic)

Participants/Inclusion and exclusion criteria

Patients with HTLV-1-induced myopathy who has passed less than 15 years of onset symptoms

Intervention groups

Intervention group: Oral administration of one 10-mg Dalfampridine capsule daily for 2 months. Control group: Oral administration placebo (the same capsule regarding color and shape compared to the intervention group) for 2 months.

Main outcome variables

The measures of MRC (muscle strength); Ashworth (spasticity); OMDS (motor disability); UDS (urinary tract disorder); T25FW:Timed 25 foot

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180618040127N4**

Registration date: **2023-06-08, 1402/03/18**

Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**

Update count: **0**

Registration date

2023-06-08, 1402/03/18

Registrant information

Name

Zohreh Vahidi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-21, 1402/03/31

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Dalfampridine on dysfunction of walking in patients with HTLV-1-induced myelopathy

Public title

The effect of Dalfampridine in HTLV-1 patients

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 Receiving other drug which influence immune system Existence of any history of seizures or epilepsy or other seizure disorders

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

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 numbers from one to forty. These numbers are defined as placebo and main drug in the pre-prepared tables with the main analyzer. In addition, the numbers and medicines have been randomly drawn by the main analyzer. we have 40 patients that are divided into two groups(ie, pill drug and placebo) thus we select 40 numbers (ie, 01to 40) witch 20 belong to cases and 20 numbers belong to control. we write the name case or control on the paper and put on of them into an open box and 40 patients incidentally pick 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 01 to 40 and delivered to the main analyzer. At the end of the study, these numbers 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

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Province

Razavi Khorasan

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9138813944

Approval date

2019-11-22, 1398/09/01

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.117

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

Medical Research Council (MRC) Scale for Muscle Strength

Timepoint

At the begging of study and months of 1 and 2

Method of measurement

Physical examination

2

Description

Spasticity score with Ashworth scale

Timepoint

At the begging of study and months of 1 and 2

Method of measurement

Physical examination

3

Description

Motor Disability score with Osame Motor Disability Score

Timepoint

At the begging of study and months of 1 and 2

Method of measurement

Physical examination

4

Description

T25FW:Timed 25 foot walk

Timepoint

At the beginning of study and months of 1 and 2

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily administration of two 10-mg capsules of Dalfampridine for 2 months. The drug company is Zahravi,

Category

Treatment - Drugs

2

Description

Control group: Control group: Daily administration of 2 placebo (capsules in same color and shape with intervention group) for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem Hospital

Full name of responsible person

Dr. Reza Boostani

Street address

Qaem Hospital, before Shariati Square, Ahmad abad Street

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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

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. Reza Boostani

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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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

Undecided - It is not yet known if there will be 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