Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Country
Iran (Islamic Republic of)

Phone
+98 51 3842 9828

Email address
vahidizh3@mums.ac.ir

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

Mashhsd

Province

Razavi Khorasan

Postal code

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 begging 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 two10-mg capsules ofDalfampridine 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
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3840 0000
Email
boostanir@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Majid Ghayour
Street address
Oposite Daneshgah 18 Street, Daneshgah Street, Central Bulding of Mashhad University of Medical Sciences (Ghoreishi)
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۹۱۹۱ ۹۱۷۷۸
Phone
+98 51 3841 2081
Email
ghayourm@mums.ac.ir
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
Street address
Before Shariati Square, Ahmadabad Street, Qaem Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۹۱۹۱ ۹۱۷۷۸
Phone
+98 51 3842 9828
Email
Boostanir@Mums.ac.ir

Person responsible for scientific 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

Street address
Before Shariati Square, Ahmadabad Street, Qaem Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۹۱۹۱ ۹۱۷۷۸

Phone
+98 51 329828

Email
Boostanir@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Fariba Zemorshidi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

Street address
Before Shariati Square, Ahmadabad Street, Qaem Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۹۱۹۱ ۹۱۷۷۸

Phone
+98 51 3842 9828

Email
zemorshidif@mums.ac.ir

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