

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the therapeutic effect of Gluronic acid in HTLV-1 patients and its effect on viral and inflammatory factors

Protocol summary

Study aim

Evaluation of clinical symptoms and serum level of inflammatory cytokines in patients with HAM/TSP after treatment with gluronic acid compared to control group

Design

A randomized, double-blinded, controlled clinical trial with a parallel group design of 40 patients

Settings and conduct

This study is conducted in the Department of Neurology and Clinic of Ghaem Hospital, Mashhad University of Medical Sciences. Patients and data analyser are blinded to the assigned groups.

Participants/Inclusion and exclusion criteria

Patients diagnosed with spastic paraparesis due to HTLV-1 infection will be included in the study. Any accompanying illness and the passing of more than 15 years from the onset of symptoms are the exclusion criteria.

Intervention groups

daily administration of two capsules of gluronic acid for 12 weeks

Main outcome variables

The measures of MRC (muscle strength); Ashworth (spasticity); OMDS (motor disability); UDS (urinary tract disorder); Serum levels of IL-1, IL-6, IL-8 and TNF-a; Proviral load levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180618040127N1**

Registration date: **2018-08-22, 1397/05/31**

Registration timing: **prospective**

Last update: **2018-08-22, 1397/05/31**

Update count: **0**

Registration date

2018-08-22, 1397/05/31

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

2018-10-02, 1397/07/10

Expected recruitment end date

2019-01-30, 1397/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of Gluronic acid in HTLV-1 patients and its effect on viral and inflammatory factors

Public title

Evaluation of the effects of Gluronic acid in HTLV-1 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

HTLV-1 positive serology Symptoms of spastic

paraparesis Presence of anti-HTLV-1 antibody in the cerebrospinal fluid MDG less than 9 Passing less than 15 years from incidence of disease symptoms Patient informed consent to participate in the study

Exclusion criteria:

Other causes of spastic paraparesis receive other drugs that affect the immune system Existence of other diseases other than HAM / TSP

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization on the individual level will be done using the online tools for random number generation. Then, the sequence will be placed in dark envelopes based on the order of appearance. The researcher chooses the first envelope for each new patient without disturbing the arrangement of the envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are blinded by placebo. The data analyzer is not aware of the study groups.

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

Province

Razavi Khorasan

Postal code

91357-345

Approval date

2018-08-11, 1397/05/20

Ethics committee reference number

IR.MUMS.REC.1397.140

2

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

Province

Razavi Khorasan

Postal code

91357-345

Approval date

2018-08-11, 1397/05/20

Ethics committee reference number

IR.MUMS.REC.1397.140

Health conditions studied

1

Description of health condition studied

patients with HTLV-1 associated myelopathy

ICD-10 code

B97.33

ICD-10 code description

Human T-cell lymphotropic virus, type I [HTLV-I] as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Medical Research Council (MRC) Scale for Muscle Strength

Timepoint

At the begging of study and 12 weeks later

Method of measurement

physical examination

2

Description

spastisite score with Ashworth scale

Timepoint

At the begging of study and 12 weeks later

Method of measurement

physical examination

3

Description

Motor Disability score with Osame Motor Disability Score

Timepoint

At the begging of study and 12 weeks later

Method of measurement

physical examination

4

Description

urinary disturbance score

Timepoint

At the begging of study and 12 weeks later

Method of measurement

physical examination and history

5

Description

serum level of inflammatory cytokines (IL-1, IL-6, IL-8 and TNF-a), Proviral load levels

Timepoint

At the begging of study and 12 weeks later

Method of measurement

serum level evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: daily usage of two capsules of 25 mg/kg of gluronic acid

Category

Treatment - Drugs

2

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem Hospital

Full name of responsible person

Dr. Fariba Zemorshidi

Street address

Ahmad abad Street, before Shariati Square. Qaem Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3840 0000

Email

Zemorshidif@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Oposite Daneshgah 18 Street, Daneshgah Street, Central Bulding of Mashhad University of Medical Sciences (Ghoreishi)

City

Mashhad

Province

Razavi Khorasan

Postal code

91357-345

Phone

+98 51 3841 2081

Email

tafaghodim@mums.ac.ir

Grant name

Research grant of Mashhad University of Medical Sciences

Grant code / Reference number

961086

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. 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
99199-91766
Phone
+98 51 3840 0000
Email
zemorshidif@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
Assistant 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
99199-91766
Phone
+98 51 3840 0000
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
99199-91766
Phone
+98 51 3840 0000
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

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Findings of the study on the therapeutic effect of gluconic acid in HTLV-1 patients and its effect on viral and inflammatory factors

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

contact with the principal investigator

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

Requesting from the principal investigator and approval of the university vice chancellor

Comments