

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Study of the efficacy of acupuncture in the control of patients' symptoms with HTLV1 Associated Myelopathy/Tropical Spastic Paraparesis (HAM/TSP)

Protocol summary

Summary

Objectives of the study: An investigation on the effect of acupuncture on the symptoms of patients infected with HTLV-1 associated myelopathy (HAM) / tropical spastic Paraparesis (TSP). The main outcome variables include spastic paraparesis, urinary incontinence, back pain, disability, and peripheral blood viral load. Intervention: In this study, the intervention is semi-experimental with pretest and posttest measure design. The patients will be neurologically examined in clinic and their peripheral blood samples will be evaluated for detection of viral load. Subsequently, the patients will receive acupuncture treatment three sessions a week for four weeks. The patients will be neurologically reexamined and for the second time the blood viral loads will be measured immediately after the intervention. Then, the same evaluation is planned to be performed three months after initial therapy using the described criteria. Inclusion criteria: Informed consent, and confirmation of HAM / TSP according to World Health Organization (WHO) criteria. Exclusion criteria: Patients who have contraindications for acupuncture such as wound or skin infection at the time of acupuncture therapy or bleeding diathesis; patients who suffer from other illness that may exacerbate the paraparesis such as vitamin B12 deficiency. The intervention is acupuncture.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031327036N1**

Registration date: **2017-05-05, 1396/02/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-05, 1396/02/15

Registrant information

Name

Amirali Ghahremani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3501 2648

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad university of medical sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy of acupuncture in the control of patients' symptoms with HTLV1 Associated Myelopathy/Tropical Spastic Paraparesis (HAM/TSP)

Public title

efficacy of acupuncture on symptoms of htlv1 patients

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Informed consent, and confirmation of HAM / TSP according to World Health Organization (WHO) criteria
 Exclusion criteria: Patients who have contraindications for acupuncture such as wound or skin infection at the time of acupuncture therapy or bleeding diathesis; patients who suffer from other illness that may exacerbate the paraparesis such as vitamin B12 deficiency. The intervention is acupuncture.

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: 20

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Single

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

Township health knowledge, Fakury boulevard, Mashhad University of Medical Sciences, Mashhad, Iran

City

Mashhad

Postal code

99191-91778

Approval date

2015-05-27, 1394/03/06

Ethics committee reference number

IR.MUMS.FM.REC.1394.112

Health conditions studied

1

Description of health condition studied

HTLV1 Associated Myelopathy/Tropical Spastic Paraparesis (HAM/TSP)

ICD-10 code

G04.1

ICD-10 code description

Tropical spastic paraplegia

2

Description of health condition studied

HTLV1 Associated Myelopathy/Tropical Spastic Paraparesis (HAM/TSP)

ICD-10 code

B33.3

ICD-10 code description

Retrovirus infections, not elsewhere classified

Primary outcomes

1

Description

Spastic Paraparesis

Timepoint

Before the intervention and After the intervention then three months after the intervention.

Method of measurement

on basis of Criterion ashworth

2

Description

incontinency

Timepoint

Before the intervention and After the intervention then three months after the intervention.

Method of measurement

on basis of Criterion ICIQ-SF

3

Description

back pain

Timepoint

Before the intervention and After the intervention then three months after the intervention.

Method of measurement

on basis of Criterion VAS

4

Description

Disability

Timepoint

Before the intervention and After the intervention then three months after the intervention.

Method of measurement

on basis of Criterion OMDS

5

Description

viral load

Timepoint

Before the intervention After the intervention, three months after the intervention.

Method of measurement

DNA copy number of virus per mononuclear cells

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention: In this study, the intervention is semi-experimental with pretest and posttest measure design. The patients will be neurologically examined in clinic and their peripheral blood samples will be evaluated for detection of viral load. Subsequently, the patients will receive acupuncture treatment three sessions a week for four weeks. The patients will be neurologically reexamined and for the second time the blood viral loads will be measured immediately after the intervention. Then, the same evaluation is planned to be performed three months after initial therapy using the described criteria.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Ghaem Hospital

Full name of responsible person

Dr Amirali Ghahremani

Street address

Ghaem Hospital, Dr. Shariati Square, beginning of Ahmadabad Avenue, Mashhad-Iran,

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Mashhad university of medical sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Knowledge and Health City,In the end of Shahid Fakouri Blvd, Mashhad,Iran

City

Mashahd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research,Mashhad university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashahd university of medical

Full name of responsible person

Dr Amirali Ghahremani

Position

Resident of Neurology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person
Dr Ali Shoeibi
Position
Associate Professor of neurology
Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty