Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 Paraparasy

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

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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