

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluating the effect of probiotics on clinical signs, inflammatory and viral factors in patients with myelopathy secondary to HTLV-1

Protocol summary

Study aim

Evaluating the therapeutic effects of probiotics on the immunopathogenesis of patients with HTLV-1-induced myelopathy and its' effect on clinical signs and viral and inflammatory factors

Design

A phase 3, triple-blinded, controlled clinical trial with two parallel group design of 40 patients in a single center

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 analyser will be unaware of study groups.

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 two 500-mg Lacto-Care capsules daily for 3 months Control group: Oral administration placebo (same capsule regarding colour and shape compared to the intervention group) for 3 months

Main outcome variables

The measures of MRC (muscle strength); Ashworth (spasticity); OMDS (motor disability); UDS (urinary tract disorder); Serum levels of IL-1, IL-4, IL-6 and IFN- γ ; viral load levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180618040127N2**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **prospective**

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

Registration date

2019-01-06, 1397/10/16

Registrant information

Name

Zohreh Vahidi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of probiotics on clinical signs, inflammatory and viral factors in patients with myelopathy secondary to HTLV-1

Public title

Evaluating the effect of probiotics in patients with myelopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

positive serology for HTLV-1 Occurrence of spastic paraparesia Existence of anti HTLV-1 antibody in cerebrospinal fluid Rule out of other etiologies of spastic paraparesia MDG less than 9 Disease duration of less than 15 years Informed consent for participating in the study

Exclusion criteria:

Existence of other comorbidities Receiving other drug which influence immune system

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization will be performed on an individual level. Foursome blocks of intervention and control groups are formed and among the 6 possible cases, 10-time selection with be performed with replacement. The generated random sequence will be placed in sealed envelopes and it will be emphasized to the researcher that they should not be rearranged.

Blinding (investigator's opinion)

Triple blinded

Blinding description

blinding the participants with placebo, blinding the outcome assessors, blindings the data analyser

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

2018-11-04, 1397/08/13

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.485

Health conditions studied

1

Description of health condition studied

HAM/TSP patients

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

Spasticity 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 medical history

5

Description

serum level of inflammatory cytokines (IL-1, IL-4, IL-6 and IFN- γ)

Timepoint

At the beginning of study and 12 weeks later

Method of measurement

Serum level evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily administration of two 500-mg capsules of Lacto-Care for 3 months. The Lacto-Capsule is an oral capsule containing the highest levels of beneficial bacteria (lactobacilli, bifidobacteria and streptococcus), along with fructooligosaccharide (contributing to the growth and activity of probiotics). The count is higher than one billion CFU and the strains and peri-biotype includes: actobacillus casei, Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Bifidobacterium breve, Bifidobacterium longum, Streptococcus thermophiles + Fructooligosaccharides (FOS)

Category

Treatment - Drugs

2

Description

Control group: Daily administration of two placebo (capsule in same color and shape with intervention group) for 3 months

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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. Fariba Zemorshidi

Position

Associate professor

Latest degree

Specialist

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