

# 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- $\gamma$ ; 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)

###### Phone

+98 51 3842 9828

###### Email address

vahidzh3@mums.ac.ir

##### 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- $\gamma$ )

### 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

##### 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)

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##### Province

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##### Phone

+98 51 3841 2081

##### Email

tafaghodim@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. Fariba Zemorshidi

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Neurology

##### Street address

Before Shariati Square, Ahmadabad Street, Qaem Hospital

##### City

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## Person responsible for scientific 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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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**

Dr. Fariba Zemorshidi  
**Position**  
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**Latest degree**  
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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