

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation TH1 and TH17 immune response mechanisms involved in the pathogenesis of Crohn's disease, following intravenous injection of autologous mesenchymal stem cells in refractory Crohn's disease patients.

Protocol summary

Summary

Our objective is to apply autologous bone marrow-derived Mesenchymal Stem Cells (MSCs) for refractory Crohn's disease; then, determine immunomodulatory effects of MSCs into TH1 and TH17 immune responses, and in the treatment of refractory Crohn's disease patients. Seventeen adult patients with refractory Crohn's disease will be entered to the study. Criteria for patient inclusion is that patients at least 18 years of age and have moderate to severe Crohn's disease, as define by a baseline Crohn's Disease Activity Index (CDAI) score between 220 and 450. Furthermore, patients have to be refractory to the standard treatment options for Crohn's disease. We define refractory patients as patients that, at some time during the course of the disease, must have received steroids, immunosuppressive agents (eg, azathioprine, 6-mercaptopurine or methotrexate) or anti-TNF therapy which did not result in an adequate response to treatment. Colonoscopy will be performed at baseline to confirm disease activity. All patients will be taken informed consent. Patients will be underwent bone marrow aspiration under local anesthesia, and Bone marrow MSCs will be isolated and will be expanded ex vivo. Two intravenous infusions of 0.5 to 2 ×10⁶ cell/kg a week apart will be used. Gene expression as well as serum levels of TGFβ, IL-17A, IL-10, IL-4,IL-23,and IFN-γ Cytokines will be determined by RT-PCR and ELISA, respectively. Also, TH1, TH17, and Treg Subpopulations will be measured by flowcytometry.

General information

Acronym

CD: Crohn's Disease, MSCs: Mesenchymal Stem Cells

IRCT registration information

IRCT registration number: **IRCT2016110630726N1**

Registration date: **2017-05-10, 1396/02/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-10, 1396/02/20

Registrant information

Name

Jalil Tavakolafshari

Name of organization / entity

Immunogenetic & cell culture department,
Immunology Research center, BuAli Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 51376276015

Email address

nazarih931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Mashhad
University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation TH1 and TH17 immune response mechanisms involved in the pathogenesis of Crohn's disease, following intravenous injection of autologous mesenchymal stem cells in refractory Crohn's disease patients.

Public title

Applying of stem cells to treat crohn's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients at least 18 years of age; Crohn's Disease Activity Index (CDAI) score between 220 and 450; Colonoscopy performed at baseline to confirm disease activity; Patients have to be refractory to the standard treatment options for Crohn's disease; such as: steroids, immunosuppressive agents (eg, azathioprine, 6-mercaptopurine or methotrexate) or anti-TNF therapy.
Exclusion criteria: History of malignancy during the course of treatment or during the last 5 years.

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **17**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional Ethics Committee Mashhad University of Medical Sciences

Street address

Ghoreishi Building, Next to the cinema Hoveizeh , University Avenue, Mashhad, Iran.

City

Mashhad

Postal code

91735-951

Approval date

2017-02-20, 1395/12/02

Ethics committee reference number

IR.MUMS.REC.1395.493

Health conditions studied

1

Description of health condition studied

Crohn disease

ICD-10 code

K50.9

ICD-10 code description

Crohn disease, unspecified

Primary outcomes

1

Description

Interleukin 23 level

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

ELISA, Pg/ml

2

Description

IFN- γ level

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

ELISA, Pg/ml

3

Description

Interleukin 10 level

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

ELISA, Pg/ml

4

Description

Interleukin 4 level

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

ELISA, Pg/ml

5

Description

TGF- β level

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

ELISA, Pg/ml

6**Description**

Th1 cell percentage

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

flow cytometry, percentage

7**Description**

Treg cell percentage

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

flow cytometry, percentage

8**Description**

Th17 cell percentage

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

flow cytometry, percentage

9**Description**

Interleukin 17 level

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

ELISA. Pg/ml

10**Description**

Interleukin 17 gene expression

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

QRT-PCR

11**Description**

Interleukin 23 gene expression

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

QRT-PCR

12**Description**

Interleukin 10 gene expression

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

QRT-PCR

13**Description**

Interleukin 4 gene expression

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

QRT-PCR

14**Description**

TGF- β gene expression

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

QRT-PCR

15**Description**

IFN- γ gene expression

Timepoint

Before intervention, Three months after intervention, six months after intervention

Method of measurement

QRT-PCR

Secondary outcomes**1****Description**

CBC

Timepoint

Before intervention

Method of measurement

cells/L , g/L , fL (femtoliters), pg (picograms)

2**Description**

Liver enzymes

Timepoint

Before intervention

Method of measurement

U/L

3

Description

Stool Exam

Timepoint

Before intervention

Method of measurement

Without unit

4

Description

Crohn's Disease Activity Index (CDAI)

Timepoint

Before intervention, Six months after intervention

Method of measurement

Standard form, SCORE

5

Description

CRP

Timepoint

Before treatment

Method of measurement

mg/L

6

Description

ESR

Timepoint

Before intervention

Method of measurement

mm/hr

Intervention groups

1

Description

Phase 1/2 Clinical Trial. Intravenous infusion autologous Bone Marrow-derived Mesenchymal Stem Cells (MSCs) for refractory Crohn's disease. Two dose infusions of 0.5 to 2 ×10⁶ cell/kg with a week interval.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Gaem hospital, Mashhad University of Medical Sciences, Mashhad, Iran.

Full name of responsible person

Dr. Hasan Vosoughinia

Street address

Gaem Hospital, Shariati Sq, Mashhad, Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for Research and Technology University, Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Vice Chancellor for Research and Technology University, Ghoreishi Building, next to the cinema Hoveize, University Avenue, Mashhad, Iran

City

Mashhad

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 and Technology University, 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**

Mashhad University of Medical Sciences

Full name of responsible person

Haniyeh Ghaffari Nazari

Position

Ph.D student in Medical immunology

Other areas of specialty/work**Street address**

Immunogenetic & Tissue Culture Department, Bu Ali Research Institute, BuAli sq, Mashhad, Iran

City

Mashhad

Postal code**Phone**

+98 51 3711 2611

Fax**Email**

nazarih931@mums.ac.ir

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Jalil Tavakkoli Afshari

Position

M.Sc., Ph.D., MT(ASCP), CLS(NCA) immunology

Other areas of specialty/work

Street address

Immunogenetic & cell culture department,
Immunology Research Center, BuAli Research Institute

City

Mashhad

Postal code

Phone

+98 51376276015

Fax

Email

tavakolaj@mums.ac.irtavakolafshari@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Haniyeh Ghaffari Nazari

Position

Ph.D student in Medical immunology

Other areas of specialty/work

Street address

Immunogenetic & Tissue Culture Department, Bu Ali
Research Institute, BuAli sq, Mashhad, Iran

City

Postal code

Phone

00

Fax

Email

nazarih931@mums.ac.ir

Web page address

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