Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Institue

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Mashhad University of Medical Scienes

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 performe 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
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Other areas of specialty/work
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Person responsible for scientific

inquiries

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Full name of responsible person
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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