Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Clinical trial Phase II (proof of concept), three arms study on amelioration of peri-anal fistula in Crohn’s disease with Warton jelly Mesenchymal Stem Cells and its Secretome

Protocol summary

Study aim
Proof of concept study on amelioration of peri-anal fistula in Crohn’s disease with Warton jelly Mesenchymal Stem Cells and its Secretome

Design
Three arm randomized trial with postoperative care and outcome assessment

Settings and conduct
Treatments will be done by 20 ml CM-MSC which is corresponded to cell secretions from 20 × 106 cells (P4-P5) (equal with 10-15mg of secretom) on average. Injection will be done by 0.5 ml monoject (29 G) insulin syringes through the fistula tract.

Participants/Inclusion and exclusion criteria
Inclusion 1. Males or females between 18-75 years old with a clinically confirmed diagnosis of Crohn’s disease 2. Medical therapy resistant perianal fistula 3. Mild to moderate Crohn’s disease activity index Exclusion 1- Any reasons which reported as side effect of interventions (Up to know there is not any report about MSC, MSC-Secretome side effects) 2- If participants would like to leave the trials for any reasons The following reasons will prevent the participate on project 1. Active infectious disease 2. Autoimmune disease 3. Pregnant patient 4. Liver or kidney insufficiency 5. Infliximab therapy in the last 3 month 6. Underlying malignancy 7. Uncontrolled diabetes 8. History of chemoradiotherapy 9. Patients with immunodeficiency 10. Severe Crohn’s disease activity index

Intervention groups
Patients as receiving MSc, Secretome, and Secretome plus hydrogel

Main outcome variables
Follow-up during 1, 3 and 6 months: including MRI, Blood test, Tissue sample (Colonoscopy). IL-10 and TNFα in serum will be quantified according to ELISA manufacturer’s instructions.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200809048342N2**
Registration date: **2022-05-21, 1401/02/31**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-21, 1401/02/31**
Update count: **0**

Registration date
2022-05-21, 1401/02/31

Registrant information

Name
Kaveh Baghaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2243 2516

Email address
kavehbaghaei@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial Phase II (proof of concept), three arms study on amelioration of peri-anal fistula in Crohn’s disease with Warton jelly Mesenchymal Stem Cells and its Secretome

Public title
Therapeutic effect of stem cell secretions on Crohn's disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Males or females between 18-75 years old with a clinically confirmed diagnosis of Crohn’s disease Medical therapy resistant perianal fistula Mild to moderate Crohn’s disease activity index

Exclusion criteria:
Any reasons which reported as side effect of interventions If participants would like to leave the trials for any reasons Active infectious disease Pregnant patient Liver or kidney insufficiency Underlying malignancy Uncontrolled diabetes History of chemoradiotherapy Patients with immunodeficiency Severe Crohn’s disease activity index

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
Because we are looking for study groups with equal sample size, limited randomization such as block randomization will be used. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps us in the intermediate analyzes during the sampling process, the number of samples assigned to each of the study groups is equal. Permuted block randomization with block size 3. Participants were assigned to three groups treatment including MSc, exosome and placebo using the block randomization method (triple blocks with equal volume). This ensures balance in the number of groups. In this study, due to the existence of three treatment groups, for 3 blocks (A: Placebo, B: MSc, C: exosome) there will be ten different manners. Randomized selection will be carried out each time by Random allocation software as follow: -ABC -BAC -ABC -BCA -BCA -CAB -CAB -CBA -BAC -BAC

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Research Institute For Gastroenterology & Liver Diseases- Shahid Beheshti Univer

Street address
Aerabi Ave., Tabnak Str., Evin, Tehran

City
tehran

Province
Tehran

Postal code
985714711

Approval date
2021-05-08, 1400/02/18

Ethics committee reference number
Ir.sbmu.rigld.rec.1400.004

Health conditions studied

1

Description of health condition studied
Patients with peri-anal fistula in Crohn’s disease

ICD-10 code
K50.813

ICD-10 code description
Crohn's disease of both small and large intestine with fistula

Primary outcomes

1

Description
Total number of soft/liquid stools in the last 7 days

Timepoint
Before starting, after 1, 3, 6 months

Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

2

Description
Flatus

Timepoint
Before starting, after 1, 3, 6 months

Method of measurement
Jorge – Wexner fecal incontinence score

3

Description
IL-10
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Blood test

4

Description
TNFα
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Blood test

5

Description
Liquid secretion
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Jorge – Wexner fecal incontinence score

6

Description
Solid secretion
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Jorge – Wexner fecal incontinence score

7

Description
Pad
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Jorge – Wexner fecal incontinence score

8

Description
Lifestyle
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Jorge – Wexner fecal incontinence score

9

Description
Abdominal pain
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

10

Description
General well-being
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

11

Description
Anti-diarrhea drug use
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

12

Description
Abdominal mass
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

13

Description
Hematocrit
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

14

Description
Arthritis/arthralgiasIritis/uveitis
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

15

Description
Erythema nodosum
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

16

Description
pyoderma gangrenosum, or apthous stomatitis
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

17

Description
Anal fissure, fistula
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

18

Description
or abscess, Fever/temperature > 100°F/37.8°C
Timepoint
Before starting, after 1, 3, 6 months
Method of measurement
Assessment of CDAI (Crohn's disease activity Index)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients receive MSC. Each patient will receive 3 injections (1 × 106 cells / Kg) first injection will be locally and then next two administrations intravenously weekly. Mesenchymal stem cells (MSCs) are multipotent adult cells with self-renewing capacities. MSCs display specific properties, such as the ability to repair damaged tissues, resulting in optimal candidates for cell therapy against degenerative diseases. In addition to the reparative functions of MSCs, evidence shows that these cells have potent immunomodulatory and anti-inflammatory properties. Therefore, MSCs are potential tools for treating inflammation-related diseases.
Category
Treatment - Other

2

Description
Control group:patients will receive placebo.
Category
Placebo

3

Description
Intervention group: secretome and MSC-secreted extracellular vesicles (Exosome). Each patient will receive 3 injections the first injection will be locally and then the next two administrations intravenously weekly. Mesenchymal stem cells (MSCs) have become key cells in therapy because of their immunosuppressive function and anti-inflammatory effects. MSCs exert immunosuppressive effects through direct contact or paracrine action. The paracrine functions of MSCs are at least partially mediated by exosomes, which are membrane vesicles, carrying abundant proteins, nucleic acids and other active molecules. MSC-exos have heterogeneity. The exosomes from different donors, tissues generations of MSCs carry different bioactive molecules. Exosomes derived from MSCs (MSC-exos) carry immunomodulatory effectors or transmit active signal molecules to regulate the biological activities of immune cells and thus mediating immune suppression.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology and Liver Diseases Research center of shahid beheshti university
Full name of responsible person
Shabnam Shahrokh\Kaveh Baghaei
Street address
Aerabi Ave., Tabnak Str., Evin
City
Tehran
Province
Tehran
Postal code
1985714711
Phone
+98 21 2243 2525
Email
kavehbaghaei@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Mohammad reza Zali
Street address
Aerabi Ave., Tabnak Str., Evin,
City
tehran
Province
Tehran
Postal code
1985714711
Phone
+98 21 2243 2525
Email
nnzali@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shabnam Shahrokh, Fakhrossadat Anaraki
Position
PI
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Aerabi Ave., Tabnak Str., Evin
City
tehran
Province
Tehran
Postal code
1985714711
Phone
+98 21 2243 2517
Email
shabnamshahrokh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Kaveh Baghaei, Massoud Soleimani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biology
Street address
Aerabi Ave., Tabnak Str., Evin
City
Tehran
Province
Tehran
Postal code
1985714711
Phone
+98 21 2243 2517
Email
kavehbaghaei@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shervin Shafiei
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Aerabi Ave., Tabnak Str., Evin
City
Tehran
Province
Tehran
Postal code
1985714711
Phone
+98 21 2243 2517
Email
shervin.shafiei1@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The part of Data including outcome measures would be available
When the data will become available and for how long
starting in April 2022
To whom data/document is available
It would be available for people working in academic institutions and people working in businesses can also apply to receive it.
Under which criteria data/document could be used
It is depend on request
From where data/document is obtainable
Corresponding: Dr. Shabnam Shahrokh Dr. Anaraki Dr. Masoud Soleimani Dr. Kaveh Baghaei

What processes are involved for a request to access data/document

-Request - Early consideration in 1 week - Conversations - Provide possible request between 2-4 weeks

Comments