

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Results assessment of allogenic implantation of human Adipose driven stem cells in external anal sphincter and fecal incontinence: a phase II clinical trial

Protocol summary

Study aim

Results assessment of autologous implantation of human Adipose driven stem cells in external anal sphincter and fecal incontinence

Design

A block randomized, double blinded, case controlled clinical trial with a parallel group design of 30 patients in two groups: control group (n=15) and cell group (n=15), enrolled between August/23/2019 and August/23/2021, and followed for six months

Settings and conduct

This study will be done in Hazrate Rasool Akram Hospital, Tehran, Iran. After human adipose derived stem cells isolation and confirmation, surgical repair of external anal sphincter will be done. Then, 20 millions cells implantation (allogenic) in external sphincter muscle in cell therapy group and placebo injection in control group will be done. Two months after intervention, fecal incontinence by wexner schedule, muscle morphology by sonography and muscle electrical activity by electromyography will be examined. The patients, researchers and the surgeon are blind to the type of treatment (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Age >25 years 2-Wexner score ≥ 8 3-Confirmation of external anal sphincter defect with endorectal ultrasonography 4-Patient consent for inclusion Exclusion criteria: 1-Pregnancy and breastfeeding 2-Participating in other trials within the past 30 days 3-History of artificial sphincter 4-Vaginal delivery within the past 6 months 5-Presence of chronic diseases 6-Autoimmune disease

Intervention groups

Intervention in cell group: External anal sphincter muscle repair and 20 millions hADSCs (suspended in 3 ml Phosphate Buffer Solution) implantation in the external anal sphincter Intervention in control group: External

anal sphincter muscle repair and 3ml placebo Solution (Phosphate Buffer Solution) injection in the external anal sphincter

Main outcome variables

Wexner Score; Rate of wound closure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160201026316N4**

Registration date: **2019-07-20, 1398/04/29**

Registration timing: **prospective**

Last update: **2019-07-20, 1398/04/29**

Update count: **0**

Registration date

2019-07-20, 1398/04/29

Registrant information

Name

Bahar Mahjoubi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 4453 3404

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Results assessment of allogenic implantation of human Adipose driven stem cells in external anal sphincter and fecal incontinence: a phase II clinical trial

Public title
Stem Cell therapy on human Fecal incontinence

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age >25 years Wexner score ≥ 8 Confirmation of external anal sphincter defect with endorectal ultrasonography
 Patient consent for inclusion
Exclusion criteria:
 Pregnancy and breastfeeding Participating in other trials within the past 30 days History of artificial sphincter Vaginal delivery within the past 6 months Presence of chronic diseases Autoimmune disease

Age
From **25 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
A permuted block randomization (block size 3) is used to implement the random allocation sequence without stratification for baseline characteristics. An independent physician generate the random allocation sequence by a computer-based program, enrolled participants, and assigned participants to interventions.

Blinding (investigator's opinion)
Double blinded

Blinding description
Four separate researchers prepare the suspensions, carry out the treatment administration, record patients' data, and data analysis. The patients and the surgeons who perform the surgery, sonographic, and physical examinations are blind to the type of treatment (double blind). To ensure the blinding of the surgeon to the type of treatment, the cell suspension and placebo are both

prepare in packages which appeared to be the same.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Iran University of Medical Sciences
Street address
 Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street, Tehran, Iran
City
 Tehran
Province
 Tehran
Postal code
 1445613131

Approval date
2019-07-15, 1398/04/24

Ethics committee reference number
IR.IUMS.REC.1398.404

Health conditions studied

1

Description of health condition studied
Faecal incontinence

ICD-10 code
R15

ICD-10 code description
Fecal incontinence

Primary outcomes

1

Description
Wexner Score

Timepoint
2 months after intervention

Method of measurement
Wexner Schedule (Standard schedule for assessment of fecal incontinence according to patient history)

2

Description
Rate of wound closure

Timepoint
Immediately after surgery to wound closure

Method of measurement

Experienced surgeon view

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

External anal sphincter action potential record in the defect site

Timepoint

Two months after intervention

Method of measurement

Electromyography

2**Description**

External anal sphincter morphology

Timepoint

Two months after intervention

Method of measurement

Endorectal Sonography

3**Description**

Amount of muscle in the external anal sphincter defect site

Timepoint

Two months after intervention

Method of measurement

Image J software

Intervention groups**1****Description**

Intervention group: External anal sphincter muscle repair and 20 millions hADSCs (suspended in 3 ml Phosphate Buffer Solution) implantation in the external anal sphincter is done.

Category

Treatment - Other

2**Description**

Control group: External anal sphincter muscle repair without implantation in the external anal sphincter is done.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Colorectal Research Center, Iran University of Medical

Sciences.

Full name of responsible person

Bahar Mahjoubi

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Colorectal Research Center, Rasoul Akram Hospital, Niayesh Street, SattarKhan Street, Tehran, Iran.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Dr. Kazem Malekouti

Street address

Vice Chancellor for research of Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway, Tehran, Iran.

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research@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Arash Sarveazad

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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Position

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Subspecialist

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General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Title and more details about the data/document

No available data

When the data will become available and for how long

No available data

To whom data/document is available

No available data

Under which criteria data/document could be used

No available data

From where data/document is obtainable

No available data

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

No available data

Comments