

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Results assessment of autologous 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 Jun 2018 and Jun 2020, 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 in to 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: **IRCT20160201026316N3**

Registration date: **2018-07-26, 1397/05/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-26, 1397/05/04**

Update count: **0**

Registration date

2018-07-26, 1397/05/04

Registrant information

Name

Bahar Mahjoubi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4453 3404

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-30, 1397/04/09

Expected recruitment end date

2020-06-29, 1399/04/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Results assessment of autologous implantation of human Adipose derived 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

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

2018-05-14, 1397/02/24

Ethics committee reference number

IR.IUMS.REC.1397.097

Health conditions studied

1

Description of health condition studied

Faecal incontinence

ICD-10 code

R15

ICD-10 code description

Faecal 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

Iran University of Medical Sciences

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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Fax

Email

research@iums.ac.ir

Web page address

<http://res.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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Subspecialist

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General Surgery

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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

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable