

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2022

Results Assessment of Human Adipose driven Stem Cells Application In Human Fecal Incontinence

Protocol summary

Summary

Objectives: Main objective: Results assessment of human Adipose driven stem cells application in human fecal incontinence Secondary objectives: Record and assessment of wexner score, endorectal sonography and of external anal sphincter electromyography before and two month after cell transplantation Design: 20 patients with anal sphincter defect and incontinence will be randomly divided into 2 groups. The control group will be done to repair the anal sphincter. In cell therapy group will be done to repair the anal sphincter and stem cell transplantation. After two months of stem cell transplantation effect on fecal incontinence will be discussed. Setting and conduct: First, human adipose derived stem cells isolation and confirmation and 6×10^6 .3ml cells implantation in to external sphincter muscle in cell therapy group will be done. Two months after cell transplantation, incontinence by wexner schedule, muscle morphology by sonography and muscle electrical activity by electromyography will be examined. Major Inclusion and Exclusion criteria: Inclusion criteria: Fecal Incontinence with sphincter deficiency; age between 25 to 55 years Exclusion criteria: Fecal Incontinence without sphincter deficiency; age less than 25 and more than 55 years. Intervention: Intervention group: External anal sphincter muscle repair and 6×10^6 .3ml cells implantation in the sphincter Control group: : External anal sphincter muscle repair and 3ml PBS injection in the sphincter main outcome measures: wexner score

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016022826316N2**
Registration date: **2016-05-07, 1395/02/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-07, 1395/02/18

Registrant information

Name

Bahar Mahjoubi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

mahjoubi.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran university of medical sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Results Assessment of Human Adipose driven Stem Cells Application In Human Fecal Incontinence

Public title

Efficacy of Stem Cells on Human Fecal Incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Fecal Incontinence with sphincter deficiency; age between 25 to 55 years
Exclusion criteria: Fecal Incontinence without sphincter deficiency; age less than 25 and more than 55 years.

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not 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

Deputy of Research and Technology, Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway, Tehran, Iran.

City

Tehran

Postal code

0098211449614535

Approval date

2016-02-15, 1394/11/26

Ethics committee reference number

IR.IUMS.REC.1394.26001

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)

Secondary outcomes

1

Description

Rate of wound closure

Timepoint

Immediately after surgery to wound closure

Method of measurement

Experienced surgeon view

2

Description

External anal sphincter action potential record in the defect site

Timepoint

Two months after intervention

Method of measurement

Electromyography

3

Description

External anal sphincter morphology

Timepoint

Two months after intervention

Method of measurement

Endorectal Sonography

4

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: Surgical repair of external anal sphincter and 6x106 .3ml human adipose driven stem cells implantation in the external anal sphincter by

Syringe
Category
Treatment - Surgery

2

Description

Control group: Surgical repair of external anal sphincter and PBS (3ml) injection in the External anal sphincter by Syringe

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

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

City
Tehan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Iran University of Medical Sciences

Full name of responsible person
Dr Seyed Ali Javad Mousavi

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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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 of Iran 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
Colorectal Research Center, Iran University of Medical Sciences

Full name of responsible person
Arash Sarveazad

Position
Faculty Member

Other areas of specialty/work

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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