

# 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  $6 \times 10^6$  .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  $6 \times 10^6$  .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

+98 21 4453 3404

###### 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.  
**City**  
Tehran  
**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  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work****Street address**

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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*