

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Results assessment of autologous implantation of human Adipose derived stem cells in augment of lower esophageal sphincter weakness leading to gastroesophageal reflux : a phase I clinical trial

Protocol summary

Study aim

Assessment of autologous implantation of human Adipose derived stem cells in augment of lower esophageal sphincter weakness leading to gastroesophageal reflux

Design

Two arm parallel group controlled randomized double blind clinical trial phase I

Settings and conduct

This study will be done at the Rasoul-e-Akram Hospital of Iran University of Medical Sciences, Tehran, Iran. Preparation of suspensions (with cell and without cell), cell injection, examinations, and data collection by blind researchers are conducted. The patient with personal consent will be blind to the study and with block randomization (block size 3) are divided into 2 groups (N = 12): Control group: Gastroesophageal reflux by injection of PBS. Cell group: Gastroesophageal reflux with 8 million cells injection. Patients in the first, second week and first month (side effects), as well as the third and sixth months after injection (endoscopy and sphincter pressure measurements) are examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 60, without hiatal herniation, without barretts, without chronic disease, without pregnancy, without morbidly obese, gastroesophageal reflux, weakness of the lower esophageal sphincter Exclusion criteria: Very old, chronic illnesses, congenital esophageal disorders, participation in a clinical trial within the last 6 months, severe weight gain, without personal consent

Intervention groups

Intervention group 1: Patients with gastroesophageal reflux due to the weakness of the lower esophageal sphincter that will be injected 8 million cells suspended in 3 ml buffered phosphate solution in the lower esophageal sphincter. Intervention group 2: Patients with

gastroduodenal reflux due to the weakness of the esophagus sphincter that will be injected 3 ml phosphate buffer solution in the lower esophageal sphincter.

Main outcome variables

The power of sphincter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041635N2**

Registration date: **2019-08-16, 1398/05/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-16, 1398/05/25**

Update count: **0**

Registration date

2019-08-16, 1398/05/25

Registrant information

Name

Shahram Agah

Name of organization / entity

Country

Iran (Islamic Republic of)

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agah.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2021-07-23, 1400/05/01

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 augment of lower esophageal sphincter weakness leading to gastroesophageal reflux : a phase I clinical trial

Public title

Strengthening the weakness of the lower esophageal sphincter leads to reflux with stem cells derived from human adipose tissue.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 60 years Without hiatal herniation Without barretts esophagus Without chronic disease Without pregnancy Without morbidly obese Gastroesophageal reflux Proven weakness of the lower esophageal sphincter

Exclusion criteria:

Those who are very old and it is difficult to get data from them Individuals with chronic illnesses, such as heart or kidney failure, and it is difficult to get data from them Individuals with congenital esophageal disorders Individuals who participated in a clinical trial within the last 6 months Those who have severe weight gain and it is difficult to get data from them Individuals who do not have personal consent to participate in the study

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be based on the block randomization method. Randomization will be done by a web software (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). The number of patients required per group (based on sample size determination) was estimated 12 patients per group (24 patients totally). Therefore, considering three random block sizes (4, 6 and 8), we will define blocks for randomization of patients. It is worth noting that random block design in the mentioned web software

will be done by another researcher who is not involved in the process of sampling and following up patients. The patient assignment sequence to the study groups is only available to the researcher, and at the time of each patient's visit to the treatment center, the sampling physician will make a phone call to the randomized design researcher to get the patient in the right group. It is worth noting that the groups will be named Group A and Group B, and the physicians involved in the treatment and follow-up of patients will not be aware of the group's original name.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are given code. The patient is blind to the study (he/she does not know whether receives cell or placebo). An endoscopic expert who injects cell suspension or the liquid in which the cell is suspended by endoscopy is blind to the study. The researcher (collector of data during post-intervention follow-up) is blind to the study.

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

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

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-05-26, 1397/03/05

Ethics committee reference number

IR.IUMS.REC.1398.341

Health conditions studied**1****Description of health condition studied**

Gastroesophageal reflux

ICD-10 code

K21.9

ICD-10 code description

Oesophageal reflux NOS

Primary outcomes

1

Description

Esophageal sphincter pressure

Timepoint

At the beginning of the study (before the intervention), the first week after the intervention, the second week after the intervention, the first month after the intervention, the third month after the intervention and the sixth month after the intervention

Method of measurement

manometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 8 million stem cells derived from human adipose tissue injection, suspended in 3 ml buffer phosphate solution, by endoscopy in the lower esophageal sphincter of patients with gastroesophageal reflux

Category

Treatment - Other

2

Description

Control group: Injection of 3 ml of liquid in which the cell is suspended, by endoscopy in the lower esophageal sphincter of patients with gastroesophageal reflux

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Colorectal Research Center, Rasoul Akram Hospital, Iran University of Medical Sciences

Full name of responsible person

Shahram Agah

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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

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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

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

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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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

Undecided - It is not yet known if there will be 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

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