

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the success rate of using human acellular tissue in reconstructive surgeries in women with anterior or apical pelvic prolapse

Protocol summary

Study aim

Investigation of human cellular tissue in reconstructive surgeries of female pelvic floor prolapse

Design

Preparation of acellularization will be done in the laboratory. A sample of the tissues will be prepared for photography and then the samples will be packed (the original tissue and several tissues in the sizes small to perform sterilization confirmation tests) and for dosimetry and irradiation and sterilization test after irradiation will be sent to the Atomic Energy Organization to ensure the sterility of the samples. After irradiation, the tissues will be photographed again to make sure that the scaffold is not destroyed and that the samples are acellular. To ensure complete sterilization of the samples after sterilization by atomic energy, all mycological, microbial, mycoplasma, HIV, HBV, HCV, CMV, EBV, HTLV tests will be performed. During the operation to repair the anterior and apical compartments, the patients are randomly divided into case and control groups. In the case group, a scaffold is used for repair, while in the control group, the repair is done with the person's own tissue. A computerized randomization list, generated by an independent statistician blinded to the trial and unrelated to the subjects involved, will use 1:1 allocation.

Settings and conduct

Surgeries are performed in the operating room of Imam Hospital. Patients are blinded to intervention allocation.

Participants/Inclusion and exclusion criteria

Women over 18 years old with anterior and apical compartment prolapse stage 2 and above and candidates for reconstructive surgery

Intervention groups

The use of human acellular tissue for repair, which is sterilized in special laboratory conditions and is used for repair in sterile conditions in the operating room.

Main outcome variables

The absence of prolapse beyond the hymen in any compartment with the standard measurement system of

pelvic organ prolapse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039247N5**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **prospective**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

Registration date

2023-03-01, 1401/12/10

Registrant information

Name

Marjan Ghaemibidgoli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8800 4858

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m_ghaemi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	intervention.
Scientific title	Placebo
Investigating the success rate of using human acellular tissue in reconstructive surgeries in women with anterior or apical pelvic prolapse	Not used
	Assignment
	Parallel
	Other design features
Public title	Secondary Ids
Investigating the success rate of using human acellular tissue in reconstructive surgeries in women with anterior or apical pelvic prolapse	empty
Purpose	Ethics committees
Treatment	
Inclusion/Exclusion criteria	1
Inclusion criteria:	Ethics committee
Women over 18 years of age Patients with prolapse of the anterior and/or apical compartment stage 2 and above, which has caused complaints including the feeling of engorgement, mass discharge, and urination disorders. candidate for reconstructive surgery	Name of ethics committee
Exclusion criteria:	Imam Khomeini Hospital Complex - Tehran University of Medical Sciences
History of pelvic floor reconstruction surgery and urinary incontinence surgery Uncontrolled diabetes Any vaginal or abdominal surgery requires the use of mesh Immunity deficiency or high dose corticosteroid use Smoking or using hookah	Street address
	East bagherkhan street
	City
	Tehran
	Province
	Tehran
	Postal code
	1419733141
Age	Approval date
From 18 years old	2023-02-14, 1401/11/25
Gender	Ethics committee reference number
Female	IR.TUMS.IKHC.REC.1401.386
Phase	
N/A	
Groups that have been masked	
- Participant - Data analyser	
Sample size	1
Target sample size: 60	Description of health condition studied
Randomization (investigator's opinion)	pelvic prolapse
Randomized	ICD-10 code
Randomization description	N81
A computerized randomization list, generated by an independent statistician blinded to the trial and unrelated to the subjects involved, will use 1:1 allocation. All participants are blinded to the list. The randomization list will be administered using identical, sequentially numbered study drug containers, and these containers will be identically labeled by two investigators who will not be involved in the recruitment of study subjects. The block random assignment method was designed by an epidemiologist using WWW.Sealedenvelop.com. The blocks will be 2 alleles of size 6. AAABBB-AABBAB-ABBBAA-AABABB-	ICD-10 code description
	Female genital prolapse
Blinding (investigator's opinion)	Primary outcomes
Single blinded	
Blinding description	1
Participants are blinded to the type of intervention. Before the study, the candidates have been given complete information about the allocation of groups. The researcher is not blind to the groups The analyst is also blind to the groups and the data for analysis is delivered to him in coded form without mentioning the type of	Description
	Primary outcome: surgical success, 12 months after surgery, absence of prolapse beyond hymen in any compartment
	Timepoint
	before the intervention and 12 months after the intervention
	Method of measurement
	standard pelvic organ prolapse measurement system (POPQ)
	Secondary outcomes

1

Description

PFDI20 questionnaire

Timepoint

before and 12 months after intervention

Method of measurement

Questionnaire score, This questionnaire has three parts: intestinal (CRAD-8), bladder (UDI-6) and pelvic (PODI-6) symptoms. Each question in each part has a score between 0-4. 0 means no complaint and 4 means it is extremely uncomfortable. The items of each comparison will be added, multiplied by 25 and divided by the number of questions. Therefore, the score of each part will be between 0-100

Intervention groups

1

Description

Intervention group: Using human acellular tissue in surgical repair in anterior and apical prolapse

Category

Treatment - Surgery

2

Description

Control group: Surgical repair in anterior and apical prolapse using one's own tissue

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Complex

Full name of responsible person

Zinat Ghanbari

Street address

East Bagherkhan Street

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2365

Email

marjan_ghaemi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Number 1, Qods street Corner, Keshavarz Boulevard, Tehran, Iran

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Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6649 2271

Email

tumspr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zinat Ghanbari

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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

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