Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of human amniotic membrane on reducing post-surgical adhesions

Protocol summary

Study aim
Investigating the effect of human amniotic membrane on reducing adhesions after laparoscopic endometriosis surgery

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3, on 40 patients, A random table of numbers between 0 and 1 will be used for randomization.

Settings and conduct
Based on the block randomization list, candidates patients for advanced endometriosis laparoscopy are selected randomly at Arash Women's Hospital. After obtaining full informed consent and a full explanation about the need for second look surgery and the use of the new and cheap hAM anti-adhesion method, in this study we place a dry patch of amniotic membrane at the adhesion site during laparoscopic surgery. And the adhesion will be checked in both groups 3 months later by ultrasound and second look surgery.

Participants/Inclusion and exclusion criteria
Inclusion: trans vaginal/rectal US of deep endometriosis, candidate for endometriosis surgical treatment, age 18-45 years, no conception desire Exclusion: no consent to continue participating in the study, presence of active infection, pregnancy and breastfeeding,genital inflammations, cardiovascular, gastrointestinal, hormonal problems, autoimmune such as lupus, etc. Cancer in the past and present, positive serulogic evidence regarding previous or current hepatitis B and C, HIV, HTLV

Intervention groups
After full informed consent and a full explanation new and cheap hAM anti-adhesion method, in this study we place a dry patch of amniotic membrane at the adhesion site during laparoscopic surgery in the case group and not to put in control group. The adhesion will be checked 3 months later by US and second look surgery

Main outcome variables
Adhesion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230917059448N1**
Registration date: **2023-11-03, 1402/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-03, 1402/08/12**
Update count: **0**

Registration date
2023-11-03, 1402/08/12

Registrant information

Name
Shirin Farhoodi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3725 5342

Email address
dr.shirinfarhoodi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of human amniotic membrane on reducing post-surgical adhesions

Public title
Evaluation of human amniotic membrane on reducing post-surgical adhesions
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
DIE in trans vaginal or trans rectal sonography surgical treatment candidate age 18-45 years no desire to pregnancy in next 3 mounths
Exclusion criteria:
no satisfy to participation active infection pregnancy or breastfeeding cardiovascular, gastrointestinal or hormonal illnesses auto immune illnesses like SLE , etc. genital system inflammations involvement to cancer in the past and present positive serology for HBS, HCV, HIV, HTLV
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method will be used. A random table of numbers between 0 and 1 will be created and each of the research participants will be placed in the intervention group if the number is between 0 and 0.5 and in the control group if the number is between 0.51 and 1.
Blinding (investigator's opinion)
Double blinded
Blinding description
participants Clinic nurse radiologist Review surgeon Data analyst The method of hiding the randomization process of the list of random allocation of patients was only at the disposal of the nurse of the laparoscopy clinic. In order to hide the random allocation process, the sequence of treatments was written on the cards in order, then the cards were placed in sealed envelopes. A random 10-digit code was written on each envelope without any order or framework, which was the identification number of the relevant patient and only the project methodologist was aware of the relevant code. When the doctor announced the eligibility of a patient, the nurse provided the envelope to the doctor and the desired treatment was carried out based on the type mentioned in the envelope. And the review of the study results was completed by the doctor who was unaware of the type of intervention. Due to the type of treatment, patients will know the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417733161
Approval date
2023-09-17, 1402/06/26
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.342

Health conditions studied

1

Description of health condition studied
Post-surgical pelvic peritoneal adhesions
ICD-10 code
N99.4
ICD-10 code description
Post-surgical pelvic peritoneal adhesions

2

Description of health condition studied
Endometriosis
ICD-10 code
N80
ICD-10 code description
Endometriosis

Primary outcomes

1

Description
endometriosis post surgical laparoscopic adhesions
Timepoint
3 months after surgery and amniotic patch

Method of measurement
sonography and second look surgery

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: administration of amniotic patch on the adhesion location during surgery
Category
Treatment - Surgery

2

Description
Control group: Intervention group: not administration of amniotic patch on the adhesion location during surgery
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women hospital
Full name of responsible person
Shirin farhoodi
Street address
cross Bagheri & Resalat avenue , Baghdarnia
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Fax
+98 21 7788 3196
Email
dr.shirinfarhoodi@gmail.com
Web page address
https://arash.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Shirin Farhoodi
Street address
Keshavarz Blvd, Qods
City
Tehran
Province
Tehran
Postal code
1417864513
Phone
+98 21 81631
Fax
+98 21 6695 4233
Email
tumspr@tums.ac.ir
Web page address
https://tums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
private
Proportion provided by this source
80
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
Persons

2

Sponsor
Name of organization / entity
Sinacell company
Full name of responsible person
Maryam Mahmoodinia Maymand
Street address
No. 162, No. 162, 16th Innovation Street,Pardis Technology Park, Jajroud Road,Kilometer 16
City
Tehran
Province
Tehran
Postal code
1657163871
Phone
+98 21 7625 0661
Email
mahmoodinia@sinacellco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sinacell company
Proportion provided by this source
20
Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shirin Farhoodi

Position

fellow-ship assistant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Farjam ave, Baghdarnia

City

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Web page address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shirin Farhhodi

Position

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

fellow-ship assistant

Latest degree

Specialist

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

According to the researchers, the data that does not endanger the confidentiality of the patient and has the approval of the ethics committee and the relevant officials can be presented.

When the data will become available and for how long

The access period starts after the publication of the article.

To whom data/document is available

public

Under which criteria data/document could be used

There is no special condition.

From where data/document is obtainable

To corresponding author.

What processes are involved for a request to access data/document

It can be received by email to the corresponding author.

Comments