

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 serologic 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 months

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

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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

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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

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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