

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Safety and efficacy of Amniotic Membrane in Asherman's syndrome management

Protocol summary

Study aim

A study on the safety of amniotic membrane uterine transplanted in patients with Asherman's syndrome

Design

The clinical Trial study in Phase 1, without Blinding,

Settings and conduct

Ten sick patients from patients referred to Sarem Hospital. Asherman's patients with intrauterine adhesions and endometrial atrophy with endometrial thickness less than 5 mm who is associated with menstruation and infertility. After selecting patients and performing HIV tests, hepatitis B and C, syphilis, history of the disease, examination, endometrial thickness, Menstrual blood volume, intrauterine adhesions, and neo-angiogenesis before using amniotic membrane and then after it. In all patients, the continued use of hormone is also used.

Participants/Inclusion and exclusion criteria

Aesherman patients with intrauterine adhesions and endometrial atrophy with an endometrial thickness of less than 5 mm

Intervention groups

Patients with Asherman's Syndrome referred to Sarem Women's Hospital

Main outcome variables

Menstrual blood volume, endometrial thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190714044201N1**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

AboTaleb Saremi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4467 0666

Email address

dr.saremi@sarem.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2019-09-11, 1398/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of Amniotic Membrane in Asherman's syndrome management

Public title

Safety and efficacy of Amniotic Membrane in Asherman's syndrome management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Asherman's patients with intrauterine adhesions and endometrial atrophy endometrial thickness of less than 5

mm normal functioning of the heart kidneys and lungs wish to complete the study

Exclusion criteria:

Unwilling to get pregnant Genital tract inflammation Cardiovascular diseases Hormonal Problems Contraceptive Indication of Relative Hormone Therapy Gastrointestinal diseases prohibits estrogen use liver or chronic hepatic failure Immune system diseases such as lupus, ... Past and present cancer Positive serologic evidence of previous or current hepatitis B and C infection as well as HIV and HTLV

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی ایران

Street address

Tehran, Hemat Highway next to Milad Tower, Iran
University of Medical Sciences

City

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Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2019-07-10, 1398/04/19

Ethics committee reference number

IR.IUMS.REC.1398.356

Health conditions studied

1

Description of health condition studied

Asherman's Syndrome

ICD-10 code

N85.6

ICD-10 code description

Intrauterine synechiae

Primary outcomes

1

Description

Menstruation

Timepoint

At baseline and 3 and 6 months after intervention

Method of measurement

Number of menstruation days, pads number

2

Description

Endometrial thickness

Timepoint

At baseline and 3 and 6 months after intervention

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Pregnancy Rate

Timepoint

12 month 3 month time frame

Method of measurement

Pregnancy routine tests

2

Description

Implantation Rate

Timepoint

Pregnancy routine tests

Method of measurement

Ultrasound

Intervention groups

1

Description

Patients with Asherman syndrome After Hysteroscopy and adhesions release, the amniotic membrane is placed on the uterine balloon stent and inserted into the uterus. Then 5cc normal saline is injected into the balloon.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sarem Women's Hospital

Full name of responsible person
Dr. Maryam Mahmoodinia Maymand

Street address
Ekbatan Town - End of Phase 3

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Tehran

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1396956111

Phone
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Fax

Email
mahmoodi.scrc@gmail.com

Web page address
<http://saremhospital.org/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sarem Fertility and Infertility Research Center

Full name of responsible person
AboTaleb Saremi

Street address
Phase 3- Ekbatan- Tehran- iran

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dr.saremi@sarem.org

Web page address
<http://saremfertility.com/>

Grant name

Grant code / Reference number

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

Title of funding source
Sarem Fertility and Infertility Research Center

Proportion provided by this source
100

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Sarem Infertility Fertility Research Center

Full name of responsible person
Dr. aboTaleb saremi

Position
Specialist physician

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Ekbatan Town, End of Phase 3, Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Sarem Infertility Fertility Research Center

Full name of responsible person
AboTaleb Saremi

Position
MD

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Sarem Women's Hospital

Full name of responsible person

Maryam Mahmoodinia Maymand

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Molecular Genetics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Ethical issue

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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