

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the efficacy of combined drug-surgical technique with radical surgery in the management of endometriosis treatment

Protocol summary

Study aim

The effectiveness of the combined drug-surgical technique in endometriosis treatment.

Design

The randomized controlled trial, parallel-group that blockade by a randomized third-party surgeon, were randomly selected and the sample size was 20 patients.

Settings and conduct

Thirty patients who referred to Sarem hospital after diagnostic laparoscopy and endometrial staging were divided into two groups randomly. In the control group, patients will be completely removed by laparoscopic surgery. In the intervention group, 3 months of drug treatment followed by laparoscopy, remnants of the lesions are removed. Data collection and analysis are done by the statistician who does not know the type of division into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Laparoscopy with the initial diagnosis and confirmation of endometriosis stages and informed consent form for inclusion Exclusion criteria: People with confirmed severe adenomyosis with advanced endometriosis, People with endometrial lesions on the pelvic nerves, People who have previously undergone endometrial surgery and People who have recently received GnRH agonist.

Intervention groups

Intervention group: Endometriosis patients who will receive 3 months of drug treatment with GnRHa. After laparoscopy, remnants of the lesions are removed and medication can be continued for another three months if there are many lesions.

Main outcome variables

Pelvic pain, periodontal pain, relapse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190714044201N2**

Registration date: **2019-12-01, 1398/09/10**

Registration timing: **retrospective**

Last update: **2019-12-01, 1398/09/10**

Update count: **0**

Registration date

2019-12-01, 1398/09/10

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

2017-12-21, 1396/09/30

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

2017-12-21, 1396/09/30

Actual recruitment end date

2019-02-19, 1397/11/30

Trial completion date

2020-02-20, 1398/12/01

Scientific title

Comparison of the efficacy of combined drug-surgical technique with radical surgery in the management of endometriosis treatment

Public title

Combined drug-surgical technique for the treatment of endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Laparoscopy with the initial diagnosis and confirmation of endometriosis stages Informed consent form for inclusion

Exclusion criteria:

People with confirmed severe adenomyosis with advanced endometriosis People with endometrial lesions on the pelvic nerves People who have previously undergone endometrial surgery. People who have recently (less than 6 months) received GnRH agonist.

Age

From **30 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through block randomization. Patient assignment to each of the intervention and control groups was performed randomly by blocking the third surgeon using a random number table to finally equal sample size in both groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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

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

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2017-12-15, 1396/09/24

Ethics committee reference number

IR.IUMS.REC.1396. 23099608823

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

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes**1****Description**

Pelvic pain

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Vaginal analogous scale

2**Description**

Pain during menstruation

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Vaginal analogous scale

Secondary outcomes**1****Description**

Recurrence of Endometriosis

Timepoint

Six months and one year after the intervention

Method of measurement

Clinical assessment

Intervention groups**1****Description**

Intervention group: Endometriosis patients who used GnRh agonists for three months then underwent laparoscopic surgery.

Category

Treatment - Surgery

2

Description

Control group: Endometriosis patients who undergo laparoscopic surgery are completely removed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarem women hospital

Full name of responsible person

Dr. AboTaleb Saremi

Street address

Sarem hospital, End of Phase 3, Ekbatan Town

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1396956111

Phone

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dr.mahmoodinia@sarem.org

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

Ekbatan Town, End of Phase 3, Sarem Hospital

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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

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Sarem Infertility Fertility Research Center

Full name of responsible person

Dr. Mahbube Rasekhi Kumle

Position

Specialist physician

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hôpital Lariboisière

Full name of responsible person

Dr. Afshin Fazel

Position

Specialist physician

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Sarem Fertility and Infertility Research Center(SAFIR)

Full name of responsible person

Dr. Maryam Mahmmodinia 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)**

Yes - There is 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

Yes - There is 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

All information on the main outcomes of the study is available for sharing.

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the results of the study.

To whom data/document is available

Official assessors of the research field of the Iran University of Medical Sciences (IUMS)

Under which criteria data/document could be used

To verify the accuracy of the analysis of the study -
Modeling for future studies - Use for future meta analyzes.

From where data/document is obtainable

Sarem Fertility and Infertility Research Center (SAFIR)

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

The official application to "Iran University of Medicalscience (IUMS)" will be communicated to the "Sarem Fertility and Infertility Research Center (SAFIR)" after being approved by the competent authorities. After receiving the request, SAFIR will contact the applicant within 10 days to answer the questions.

Comments