Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the effect of treatment with laparoscopic salpingostomy, laparotomy and methotrexate treatment on the results of hysterosalpingography in patients with ectopic pregnancy

Protocol summary

Study aim
The effect of laparoscopic salpingostomy, laparotomy, and methotrexate treatment on hysterosalpingography results

Design
A randomized clinical trial with the parallel groups, without blinding

Settings and conduct
In this study, 99 patients with ectopic pregnancy will be included in the study and will be randomly divided into three groups. These patients will be treated with laparoscopic salpingostomy, laparotomy and methotrexate treatment, respectively. They undergo hysterosalpingography three months after the intervention. Ectopic pregnancy mass size and infection will then be assessed and recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria include mass diameter less than 3.5 cm, stable hemodynamics, Beat human chorionic gonadotrophin (BHCG) less than 5000 mIU/mL, and satisfaction to participate in the study. Exclusion criteria include ectopic pregnancy recurrence, fetal cardiac activity in ectopic pregnancy, having liver and kidney disease, having lung disease, having an active stomach ulcer, and breastfeeding.

Intervention groups
Intervention group 1: Patients in this group are treated with laparoscopic salpingostomy. Intervention group 2: Patients in this group undergo laparotomy. Intervention group 3: Patients in this group will be treated with methotrexate. All patients undergo hysterosalpingography three months after the intervention. It was done three months after the intervention, 2-5 days after onset of the menstrual period, but before the ovulation period, so that it was ensured about the subjects were not pregnant.

Main outcome variables
Ectopic pregnancy mass size; infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201111049352N1**
Registration date: **2020-12-06, 1399/09/16**
Registration timing: **retrospective**

Last update: **2020-12-06, 1399/09/16**
Update count: **0**

Registration date
2020-12-06, 1399/09/16

Registrant information

Name
Mina Ahmadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3779 0013

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
2019-04-21, 1398/02/01

Actual recruitment end date
2020-07-19, 1399/04/29

Trial completion date
2020-07-19, 1399/04/29

Scientific title
Evaluation of the effect of treatment with laparoscopic salpingostomy, laparotomy and methotrexate treatment on the results of hysterosalpingography in patients with ectopic pregnancy

Public title
The effect of laparoscopic salpingostomy, laparotomy, and methotrexate treatment on hysterosalpingography results

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Mass diameter less than 3.5cm Stable hemodynamics Beat human chorionic gonadotrophin (BHCG) less than 5000 mIU/mL Satisfaction to participate in the study

Exclusion criteria:
Ectopic pregnancy recurrence Fetal cardiac activity in ectopic pregnancy Having liver and kidney disease Having lung disease Having an active stomach ulcer Breastfeeding

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **99**
Actual sample size reached: **99**

Randomization (investigator's opinion)
Randomized

Randomization description
99 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study 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 Isfahan University of Medical Sciences

Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2018-09-30, 1397/07/08

Ethics committee reference number
IR.MUI.MED.REC.1398.268

Health conditions studied

1

Description of health condition studied
Ectopic pregnancy

ICD-10 code
O.00

ICD-10 code description
Ectopic pregnancy

Primary outcomes

1

Description
Ectopic pregnancy mass siza

Timepoint
Three months after intervention

Method of measurement
Imaging

2

Description
Infection

Timepoint
Three months after intervention

Method of measurement
Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group I: Patients in the first group undergo laparoscopic salpingostomy. So that, after the pneumoperitone is generated by the electronic pneumoperitoneum storz electronic device, an 11 mm trocar enters the abdomen from the umbilicus, then a laparoscope connected to the cold xenon light enters from the trocar and enters the outer end of the trocar attaches to the camera. After examining the abdomen and pelvis under direct vision, two 5.5 mm trocars are implanted in the lower abdomen to pass surgical instruments. First, the tube is determined and released, then a 1-2 cm incision is made in the antisentric section of the tube using a laser, micro electrode or scissors. The pregnancy product often protrudes spontaneously and gently comes out of the tube. Or is removed using hydrodissection and laparoscopic forceps.

Category

Treatment - Surgery

2

Description

Intervention group 2: Patients in the second group undergo laboratory surgery. So that, after opening the abdominal wall layers and exposing the uterus and cardiac tube, a 10-15 mm incision is made in the anticentric margin on the ectopic pregnancy. Pregnancy products usually come out of the incision site. Pregnancy products can be carefully removed or removed using a high-pressure washing system that removes the trophoblastic tissue more completely.

Category

Treatment - Surgery

3

Description

Intervention group 3: Patients in the third group, methotrexate at a dose of 50 mg/m2, will be given a single dose intramuscularly.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahran Hospital

Full name of responsible person
Mina Ahmadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan 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?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Behnaz Khani

Position
Assistant 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
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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available