

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparing the efficacy of methotrexate and laparoscopic salpingostomy in treating patients with ectopic pregnancy and their role in fallopian tubes patency

Protocol summary

Summary

The aim of this study is to compare the efficacy of methotrexate (MTX) as a medical treatment with laparoscopic salpingostomy as a surgical approach in patients with ectopic pregnancy. Furthermore, the effects of these treatments on fallopian tubes patency will be studied. Diagnosis of ectopic pregnancy will be made based on an adnexal mass without cardiac function in transvaginal ultrasound and a B-hCG level below 5000 IU/L. This study is a randomized clinical trial. Forty patients with ectopic pregnancy and hemodynamic stability will be randomly assigned into two groups. The patients in the first group will receive two doses of MTX (50 mg/m²) and the other group will undergo a laparoscopic salpingostomy. Complete treatment is defined as a decrease in B-hCG level up to non-pregnancy levels. Additionally, eight weeks after the time that B-hCG test became negative, fallopian tubes patency will be assessed by hysterosalpingography

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212121556N49**

Registration date: **2012-12-23, 1391/10/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-23, 1391/10/03

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-12-30, 1391/10/10

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the efficacy of methotrexate and laparoscopic salpingostomy in treating patients with ectopic pregnancy and their role in fallopian tubes patency

Public title

comparing the efficacy of methotrexate and laparoscopic salpingostomy in treating patients with ectopic pregnancy and their role in fallopian tubes patency

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 1- hemodynamic stability 2- ectopic mass size below 4 cm 3- patients' commitment for

complete treatment and follow up 4- absence of MTX treatment contraindication Exclusion criteria: 1- breast feeding 2- immune deficiency 3- abnormalities in hematologic system including anemia, locopenia, thrombocytopenia 4- known hypersensitivity reaction to MTX 5- acute respiratory disease 6- acute peptic ulcer 7- alcoholism 8- clinical malfunction of liver and kidney 9- evidence of acute intraabdominal bleeding 10- evidence of cardiac function in the embryo 11- clinical sign and symptom of ectopic pregnancy, or B-hCG level below 5000 IU/L (with mild sign and symptoms)

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Ethic Committee of Tehran University of Medical Sciences

Street address

Ethic Committee of Tehran University of Medical Sciences, 16 azar avenue, Keshavarz bolvar

City

tehran

Postal code**Approval date**

2012-10-22, 1391/08/01

Ethics committee reference number

17892

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

ectopic pregnancy

ICD-10 code

000

ICD-10 code description

Ectopic pregnancy

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

B-hCG level

Timepoint

at the end of study

Method of measurement

blood sampling

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

fallopian tubes patency

Timepoint

eight weeks after the time that B-hCG test became negative

Method of measurement

histerosalpingography

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

MTX (two doses)

Category

Treatment - Drugs

2**Description**

laparoscopic salpingostomy

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash Hospital

Full name of responsible person

Dr. Ladan Kashani

Street address

Tehran Pars, Rashid Street, Arash Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Foutohi

Street address

Tehran University of Medical Sciences, Keshavarz Blvd

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ladan Kashani

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Assistant Prof.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty