

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The comparative study of the effects of methotrexate and combination of methotrexate-mifepristone in treatment of ectopic pregnancy

Protocol summary

Summary

The purpose of this study is to compare the effects of methotrexate and the combination of methotrexate - mifepristone in the treatment of ectopic pregnancy. In this double-blind single center study, 66 patients admitted to Imam Reza Hospital with a diagnosis of ectopic pregnancy will be recruited. The patients with stable hemodynamic status and adnex mass smaller than 4 cm BHCG level less than 1500mIU/ml, and no history of any specific disease, are randomized into two different groups to receive single dose of methotrexate 50mg/m² intramuscular plus 600mg mifepristone orally or only a single dose of methotrexate with oral placebo. Beta HCG level, renal and liver function tests are examined in the fourth and seventh days after administration of these drugs. The most important outcome of this study is the success rate of treating ectopic pregnancy. This study will be conducting for 18 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010033461N3**

Registration date: **2010-10-31, 1389/08/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-31, 1389/08/09

Registrant information

Name

Firoozeh Veisi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1823 4276

Email address

f_veisi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative study of the effects of methotrexate and combination of methotrexate-mifepristone in treatment of ectopic pregnancy

Public title

Effects of methotrexate and combination of methotrexate-mifepristone in treatment of ectopic pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: stable Hemodynamic state, Without Bleeding or hemo-peritoneum, un ruptured ectopic pregnancy, ectopic pregnancy mass without FHR, ectopic pregnancy mass smaller than 4cm, BHCG less than 1500 mlu/ml, no contradiction of use of methotrexate or mifepristone Exclusion criteria: decrease in serum BHCG, BHCG less than 1500 mlu/ml and depletion after 48 h,

history of liver and renal diseases, hematologic or others disorders such as: glaucoma, porphyria, thalassemia, ulcerative colitis, heart diseases, psychological diseases, corticosteroid use more than 6 months, prior sensitivity to methotrexate or mifepristone

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee, Kermanshah University of Medical Sciences

Street address

Imam Reza hospital, Parastar Blvd., Kermanshah

City

Kermanshah

Postal code

6714415333

Approval date

2010-06-08, 1389/03/18

Ethics committee reference number

7/420/202 /پ

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

Pregnancy with abortive outcome

ICD-10 code

O00

ICD-10 code description

Pregnancy with abortive outcome

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

Ectopic Pregnancy treatment

Timepoint

Days 4, 7, 11, and 14

Method of measurement

Beta hCG level

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

need to second methotrexate injection

Timepoint

from 4th to 7th day

Method of measurement

BhcG level

2**Description**

Rate of infection

Timepoint

4th, 7th and 11th day after intervention

Method of measurement

temperature more than 38 degree centigrade

3**Description**

surgical intervention

Timepoint

4th day after intervention

Method of measurement

laparotomy

4**Description**

Number of days required to reduce BhcG level

Timepoint

after 4th day

Method of measurement

Beta hcG level

5**Description**

hospital stay

Timepoint

from admission to discharge

Method of measurement

Number of hospitalization dayshospitalization

Intervention groups

1

Description

50mg/m2 methotrexate IM, with single dose oral placebo (same as mifepristone)

Category

Placebo

2

Description

single dose of methorexate IM + 600mg mifeipoistone orally

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Kermanshah University of Medical Sciences

Full name of responsible person

Street address

Imam Reza Hospital, Parastar Blvd., Kermanshah University of Medical Sciences,

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Firoozeh Veisi

Street address

Imam Reza hospital, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Firoozeh Veisi

Position

Assistant professor of OB-GYN

Other areas of specialty/work

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Firoozeh Veisi

Position

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Contact

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Position

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Web page address**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