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 than1500 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
laparatomy

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 mifepoistone oraly
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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Web page address

Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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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