Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between single and double dose of Methotrexate in Ectopic Pregnancy

Protocol summary

Summary

The aim of this double blind trial is to compare the response to treatment by single and double dose of Methotrexate in Ectopic Pregnancy. Inclusion criteria: 1- Adenexal mass with a size of 4 cm at maximum; 2- β-hCG titration level less than 15000 mIU/mL; 3- Stable hemodynamic status; 4- No fetal heart activity in gestational sac; 5- consent for Methotrexate therapy and follow -up; 6- Normal laboratory tests. The cases will be hospitalized patients who suffer from EP with inclusion criteria in Al-Zahra Hospital. The sample size will be 146 women recognized as tubal EP by clinical signs ,transvaginal sonography and β-hCG titration level . After determining basic β-hCG titration level, These patients will be divided in two groups (single and double dose of Methotrexate) randomly via a computer-generated random numbers table. The single dose group will receive 50 mg/m2 Methotrexate intramuscularly on day 0 and the double dose group will receive the same dose on days 0 and 4 .All cases will be hospitalized during the first week of treatment. Then, they will be followed by referring to the gynecologic clinic at Al-Zahra hospital and β–hCG titration level and side effects will be assessed weekly . two groups will be compared according to : 1-Success rate that will be determined as a decrease of 15% or more in serum β–hCG titration level from day 4 to day 7 and subsequent decrease to lesser than 10 mIU/mL in 6 weeks without surgical intervention or repeated dosage ; 2- duration of treatment ; 3-Side effects of Methotrexate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051110089N3**
Registration date: **2013-09-03, 1392/06/12**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-09-03, 1392/06/12

Registrant information

Name
Roya Faraji Darkhaneh
Name of organization / entity
Guilan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Guilan university of medical sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between single and double dose of Methotrexate in Ectopic Pregnancy

Public title

Comparison between single and double dose of Methotrexate in Ectopic Pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Andexal mass with a size of 4 cm at maximum ; 2- β–hCG titration level less than15000 mIU/mL; 3- Stable hemodynamic status -Blood Pressure > 90/60 mmHg and nonexistence of tachycardia (Pulse Rate less than 100/min); 4-No fetal heart activity in gestational sac; 5- Consent for Methotrexate therapy and follow-up; 6- Normal laboratory tests(Platelet count more than 120000/µL , Serum Creatinin less than 1.2mg/dL or Aspartate aminotransferase less than double of normal level). Exclusion criteria: This study has not exclusion criteria .

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This is a Double blind trial. The patient & the person who registers the data are not aware of the dosage of medication. Medication is prescribed by someone else.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Ethics Committee of Guilan University of Medical Sciences, Gaz Square

City

Rasht

Postal code

Approval date

2013-04-20, 1392/01/31

Ethics committee reference number

9210029710

Health conditions studied

1

Description of health condition studied

Tubal pregnancy

ICD-10 code

O00.1

ICD-10 code description

Fallopian pregnancy

Primary outcomes

1

Description

Treatment response in terms of basic β-hCG titration level by ELIZA technique

Timepoint

After first week of treatment and 6 weeks follow-up period

Method of measurement

Determining β-hCG titration level before treatment by ELIZA technique

2

Description

Therapeutic response to methotrexate

Timepoint

Day 4 and day 7, and its repetition weekly until 6 weeks

Method of measurement

Visit the patient and determining serum β–hCG titration level by ELIZA technique

3

Description

Treatment response in terms of longest ectopic mass diameter on Transvaginal Sonography

Timepoint

After first week of treatment and 6 weeks follow-up period

Method of measurement

Determining the longest ectopic mass diameter in terms of Ultrasound report before treatment

Secondary outcomes

1

Description

Follow-up days

Timepoint

After treatment and since first week of follow-up

Method of measurement

Duration of Treatment and follow-up until β–hCG titration level declined to less than 10 mIU/mL in terms of day by ELIZA technique

2

Description
Methotrexate side effects(Abdominal pain,Gastrointestinal symptoms,Alopecia ,Mucositis,Leukocyte count<4000,Platelet count<120000, Aspartate aminotransferase more than double level of normal).
Timepoint
After treatment and on first week of follow up
Method of measurement
History, checking liver function tests and Complete Blood Count (CBC)

Intervention groups

1

Description
After diagnosis of tubal EP and determining basic β–hCG titration level and checking kidney, liver function tests and Complete Blood Count (CBC) Methotrexate with a brand name EBETREX manufactured by EBEWE company, Austria is given to group (I) 50 mg/m2 intramuscularly on day 0 and day 4.
Category
Treatment - Drugs

2

Description
After diagnosis of tubal EP and determining basic β–hCG titration level and checking kidney, liver function tests and Complete Blood Count (CBC) Methotrexate with a brand name EBETREX manufactured by EBEWE company, Austria is given to group (II) 50 mg/m2 intramuscularly on day 0.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital, Guilan University of Medical Sciences
Full name of responsible person
Roya Faraji Darkhane
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Guilan University of Medical Sciences
Full name of responsible person
Abdolrasol Sobhani
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City
Rasht
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, Guilan 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

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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