Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of single dose and multiple dose methotrexate in treatment of unruptured tubal pregnancy and fertility 1 year after treatment

Protocol summary

Summary

Objectives: This study is aimed to compare the effect of single dose and multiple dose methotrexate in treatment of tubal pregnancy and fertility 1 year after treatment. Design: Prospective randomized clinical trial. Setting and conduct : Tertiary regional and teaching hospital. Participants including major eligibility criteria: Seventy patients, with gestational age less than 20 weeks; absence of bleeding in evidences of laparoscopic surgery and vaginal sonography, β -hCG less than 15000 mlU per mL undergoing treatment with methotrexate in Yazd Shahid Sadoughi Hospital during 2010-2011 , were included and patients with Creatinine levels more than 1.5 mg/kg, Platelet levels more than 100000/ml, W.B.C levels more than 2000/ml, Higher than 2 times increased liver enzyme levels were excluded. Patients were randomized into two groups of 35 each, using a table of random numbers. Intervention: Group I patients received methotrexate (50 mg per m2 IM on day one) and multiple dose (1 mg per kg per day) on days 1,3,5,7 and citrovoram factor (0.1mg per kg per day) were administered for 2,4,6,8 days. Main outcome measures (variables): Adverse events,resolution of pregnancy without surgical treatment and Success rate of methotrexate treatment and fertility outcome in each group. The medications are coded and delivered to the patients by and individual not aware of the research process. A blind stuff assessed success rates of treatment by measuring drop in serum β - hCG level. Also, Researcher was unaware to each groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112178435N1**
Registration date: **2011-12-27, 1390/10/06**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-12-27, 1390/10/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadughi University of Medical Sciences Yazd, Bahonar Sq.

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-10-23, 1389/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of single dose and multiple dose methotrexate in treatment of unruptured tubal pregnancy and fertility 1 year after treatment

Public title

Comparison of effect and side effects of single dose and multiple dose methotrexate in treatment of tubal

pregnancy and fertility 1 year after treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria gestational age less than 20 weeks; absence of bleeding in evidences of laparoscopic surgery and vaginal sonography; stable hemodynamic state; tubal mass equal or less than 4 cm in diameter; absence of fetal heart beat; β -hCG less than 15000 mlU/mL, and leaning of patient to next pregnancy. Exclusion criteria Creatinine levels more than 1.5 mg/kg, Platelet levels more than 100000/ml, W.B.C levels more than 2000/ml, Higher than 2 times increased liver enzyme levels

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Ethics committee of Shahid Sedughi University of Medical Sciences

Street address

Shahid Bahonar seq.

City

Yazd

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

5693 . 1.17 . p

Health conditions studied

1

Description of health condition studied

Treatment of unruptured tubal pregnancy

ICD-10 code

O00, O01,O

ICD-10 code description

Treatment of unruptured ectopic pregnancy

Primary outcomes

1

Description

Success rates of treatment

Timepoint

Interval 48 hrs. on days 1,3,5,7

Method of measurement

Measurement of β - hCG level

Secondary outcomes

1

Description

Fertility

Timepoint

12 months after treatment

Method of measurement

Question about fertility

Intervention groups

1

Description

In the study group, single dose regimen, 50mg /m2 intramuscular methotrexat

Category

Treatment - Drugs

2

Description

In the control group, Intramuscular methotrexate (1mg/kg/day) was given on days 1,3,5,7 and citrovoram factor (0.1mg/kg/day) were administered for 2,4,6,8 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadughi Hospital

Full name of responsible person

Afsar Tabatabaii Bafghi

Street address

Mahdiyeh St.

City

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Sadughi University of Medical Sciences
Full name of responsible person
Fatemeh Ezedini
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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
Vice chancellor for research, Shahid Sadughi 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
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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