Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy and side effects of both single-dose and two-dose methotrexate therapy in ectopic pregnancy in patients referred to Imam Khomeini Hospital in Ahvaz

Protocol summary

Summary

In this study we compared single dose with double dose of methotoxate (MTX) therapy for treatment of 76 patients with ectopic pregnancy referring to Imam Khomeini hospital of Ahvaz. Inclusion criteria were, healthy women with stable hemodynamic condition and BHCG less than 15000 mU/mL .Women who had a history of liver and kidney disease or blood dyscrasia, breastfed were excluded from the study. the sample size was calculated 76 patients (38 in each single or double dose group). In single dose group, 50mg/m2 methotrexate was administered in day 0, while in the double dose group; patients received two doses in day 0 and 4. BHCG of both groups were measured in 4th and 7th day of hospitalization. A 15% decrease in BHCG level considered as a successful treatment. . If the rupture of fallopian tube has happened, patient underwent the immediate surgery. The necessity of surgery was determined in both groups. Every woman remained hospitalized until their BHCG reached 200 mU/mL . Beside of BHCG level the duration of hospitalization also determined for single dose and double dose groups. The side effects of methotrexate, function of liver and kidney were checked in each participant one week after completion of treatment , If liver trans aminase increased 1.5 times more than normal, or creatinine increased to 1.5mg/dL, WBCs decreased to 2000 or platelets declined fewer than 100000, these were assumed as drug complications and compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080523519N1**
Registration date: **2015-08-18, 1394/05/27**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-08-18, 1394/05/27

Registrant information

Name

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Name of organization / entity

Ahwaz Jondishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jondishapur University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and side effects of both single-dose and two-dose methotrexate therapy in ectopic pregnancy in patients referred to Imam Khomeini Hospital in Ahvaz

Public title

Efficacy of two-dose methotrexate therapy in ectopic pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: stable hemodynamic condition; low free fluid intrapritoneal on ultrasound; BHCG less than 15000 mU/mL; no history of liver or renal disease or blood dyscrasia; no breastfeeding and patient satisfaction. Exclusion criteria: unwillingness to continue participation in the study; unstable hemodinamic condition.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

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

Ahwaz Jundishapur University of Medical Sciences

Street address

Ahwaz Jundishapur University of Medical Sciences, Daneshgah Sq.

City

Ahwaz

Postal code

6135-15794

Approval date

2013-05-04, 1392/02/14

Ethics committee reference number

AJUMS.REC.1392.19

Health conditions studied

1

Description of health condition studied

Ectopic pregnancy

ICD-10 code

O00.9

ICD-10 code description

Ectopic pregnancy, unspecified

Primary outcomes

1

Description

The overall success(15% reduction in β-HCG level)

Timepoint

At days: 4 and 7

Method of measurement

Lab test

Secondary outcomes

1

Description

The time BHCG reached 200 mU/mL

Timepoint

daily

Method of measurement

Lab test

2

Description

Side effects

Timepoint

7 days after treetment

Method of measurement

If liver trans aminase increased 1.5 times more than normal, or creatinine increased to 1.5mg/dL, WBCs decreased to 2000 or platelets declined fewer than 100000, these were assumed as drug complications

3

Description

The rate of surgery

Timepoint

During the follow-up period

Method of measurement

If the rupture of fallopian tube has happened, patient underwent the immediate surgery

Intervention groups

1

Description

In single dose group 50mg/m2 methotrexate was administered in day 0

Category

Treatment - Drugs

2

Description
In the double dose group; patients received two doses (50mg/m2 methotrexate) in day 0 and 4
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Ahwaz
Full name of responsible person
Sara Safyari
Street address
Imam Khomeini Hospital, Azadeghan street
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Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahwaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Nader Saki
Street address
Ahwaz Jundishapur University of Medical Sciences, Daneshghah square
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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
Ahwaz Jundishapur 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
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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