

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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 methotrexate (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/m<sup>2</sup> 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

Sara Safyari

###### Name of organization / entity

Ahvaz Jondishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4421 4270

###### Email address

safyari.s@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Ahvaz 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 intraperitoneal 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 hemodynamic 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  $\beta$ -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 treatment

#### **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/m<sup>2</sup> methotrexate was administered in day 0

#### **Category**

Treatment - Drugs

## 2

### Description

In the double dose group; patients received two doses (50mg/m<sup>2</sup> 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

##### City

Ahwaz

## 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,  
Daneshgah square

##### City

Ahwaz

##### 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

Ahwaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Sara Safyari

#### Position

Speciality doctorate degree in Obstetrics and Gynecology

#### Other areas of specialty/work

#### Street address

Emam Khomeini hospital of Ahwaz, Azadegan St.

#### City

Ahwaz

#### Postal code

#### Phone

+98 612227317

#### Fax

#### Email

dr\_safyari@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Najmie Saadati

##### Position

Speciality doctorate degree in Obstetrics and Gynecology/Associate Professor

##### Other areas of specialty/work

##### Street address

Emam Khomeini hospital of Ahwaz, Azadegan St.

##### City

Ahwaz

##### Postal code

##### Phone

+98 612227317

##### Fax

##### Email

NIL2F@Yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Najmie Saadati

##### Position

Speciality doctorate degree in Obstetrics and Gynecology/Associate Professor

##### Other areas of specialty/work

##### Street address

Emam Khomeini hospital of Ahwaz, Azadegan St.

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##### Fax

##### Email

NIL2F@Yahoo.com

##### 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*