

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of Double and Single dose Methotrexate Protocols in the treatment of patients with tubal pregnancy

Protocol summary

Summary

This is a double-blind clinical trial to compare single and double doses methotrexate protocol for the treatment of ectopic pregnancy in Alzahra University Hospital. Inclusion criteria are: stable hemodynamic state; the initial β -hCG lower than 10000 mIU/ml; no fetal heart activity by transvaginal sonography and; the request of fertility preservation. exclusion criteria are: creatinine above 1.5 mg/dl; platelets count lower than 100000/ml and; increased liver enzymes. Patients which are candidates for medical therapy are randomly divided into two groups, single and double doses methotrexate protocols. In the first group, we will administer 50 mg/m² methotrexate IM on day 1, in the second group we will administer methotrexate on day 1 and 4, the serum day 4 and 7 β -hCG will be compared between the two groups. If there is a drop of 15%, the treatment is considered effective, if not the next doses of methotrexate are administered on day 7, and again on day 11. If there is not a drop of 15% of β -hCG on day 14, the patient will be operated. Before each methotrexate administration, CBC, liver, and kidney laboratory tests will be done and the side effects like gastrointestinal symptoms, abdominal pain, epigastric pain, mucositis, hair loss will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610085485N6**
Registration date: **2016-11-27, 1395/09/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-27, 1395/09/07

Registrant information

Name

Nazli Navali

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medecine

Country

Iran (Islamic Republic of)

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+98 41 1330 2879

Email address

navalin@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center, Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Double and Single dose Methotrexate Protocols in the treatment of patients with tubal pregnancy

Public title

Double and Single dose Methotrexate regimens in the treatment of ectopic pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: stable hemodynamic state; adnexal mass diameter lower than 4 cm; the initial β -hCG lower than 10000 mIU/ml; no fetal heart activity by transvaginal sonography and, the request of fertility preservation. exclusion criteria are: creatinine above 1.5 mg/dl; platelets count lower than 100000/ml; white blood cells count lower than 2000/ml and; increased liver enzymes.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Tabriz University of Medical Sciences

Street address

Research Deputy of Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

IR.TBZMED.REC.1395.597

Health conditions studied**1****Description of health condition studied**

medical treatment of ectopic pregnancy

ICD-10 code

O00.1

ICD-10 code description

Tubal pregnancy Fallopian pregnancy

Primary outcomes**1****Description**

beta-hCG decrease

Timepoint

days 7, 11 and,14

Method of measurement

blood exam

Secondary outcomes**1****Description**

abdominal pain

Timepoint

daily and per patient report

Method of measurement

by visiting the patient and patient report

2**Description**

drug side effects

Timepoint

days 4, 7 and, 11

Method of measurement

physical exam and blood tests

Intervention groups**1****Description**

In the first group (single dose), we will administer 50 mg/m² methotrexate IM on day 1, the serum day 4 and 7 β -hCG will be compared. If there is a drop of 15%, the treatment is considered effective, if not the next doses of methotrexate are administered on day 7, and again on day 11 if not effective with the same rule. If there is not a drop of 15% of β -hCG on day 14 in comparison to day 11, the drug therapy is failed and the patient will be operated.

Category

Treatment - Drugs

2**Description**

In the second group (double dose), we will administer 50 mg/m² methotrexate IM on day 1 and 4, the serum day 4 and 7 β -hCG will be compared. If there is a drop of 15%, the treatment is considered effective, if not the next doses of methotrexate are administered on day 7, and again on day 11 if not effective with the same rule. If there is not a drop of 15% of β -hCG on day 14 in comparison to day 11, the drug therapy is failed and the

patient will be operated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Nazli Navali

Street address

Artesh street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Women's Reproductive Health Research Center, Vice
chancellor for research, Tabriz University of Medi

Full name of responsible person

Dr. Elahe Saheb Olad Madarec

Street address

Artesh street

City

Tabriz

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Women's Reproductive Health Research Center, Vice
chancellor for research, Tabriz University of Medi

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

Tabriz University of Medical Sciences

Full name of responsible person

Nazli Navali

Position

infertility fellowship/associate professor

Other areas of specialty/work

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Web page address

**Person responsible for scientific
inquiries**

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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