Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 m 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)

Phone
+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 comparision 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 comparision 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

Street address

Artesh street, Alzahra Hospita, infertility department

City

Tabriz

Postal code

5138665793

Phone

+98 41 3554 1221

Fax

Email

navalin@tbzmed.ac.ir

Web page address

Person responsible for scientific 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

Street address

Infertility department, Alzahra Hospital, Artesh street

City

Tabriz

Postal code

5138665793

Phone

+98 41 3554 1221

Fax

Email

navalin@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Nazli Navali

Position

associate professor/infertility fellowship

Other areas of specialty/work

Street address

Infertility department, Alzahra Hospital, Artesh street

City

Tabriz

Postal code

5138665793

Phone

+98 41 3330 9697

Fax

+98 35566449

Email

navalin@tbzmed.ac.ir

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