

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of pulsed Actinomycin versus 5-day Methotrexate for the treatment of low-risk gestational trophoblastic disease in patients

Protocol summary

Summary

The purposes of the study: Comparison of the recurrence and remission rate as well as the duration and complications of the treatment or patients with low risk gestational trophoblastic neoplasm by either pulse Actinomycine and Methotrexate. Study design: Among patients with gestational trophoblastic neoplasm who attended MirzaKuchek Khan and Imam Khomeini Hospital through years 2011 to 2014 a sample of 44 patients were selected (the volume of the sample calculated by convenience method) and filter through exclusion and inclusion criteria. Inclusion criteria: Postmolar Gestational trophoblastic neoplasm who meet FIGO stage 1,2,3 criteria. Patients must have undergone evacuation of a complete or partial hydatidiform mole and then meet the criteria : Less than 10% decrease in the β HCG level using as a reference the first value in the series of 4 values taken over a period of 3 weeks ; More than 20% sustained rise in the β HCG taking as a reference the first value in The series of 3 values taken over a period of 2 weeks (more than 50); Persistently elevated β HCG level a period of 6 months (more than 50); W.H.O. risk score 0-6; Patients must have normal hepatic, hematologic, and renal function Exclusion criteria: Patients who do not have GTN as defined Criteria; Patients who have previously been treated with cytotoxic chemotherapy. However, patients who received prior low-dose methotrexate for treatment of an ectopic pregnancy will be eligible for this study; Patients with placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); Patients who wish to breast-feed during treatment; Patients with non-gestational choriocarcinoma; Disease progression; Pregnancy. Interventions: Group 1: Actinomycin pulse protocol (1.25 miligram per square meter) every 14 days intra vascular (maximum dose 2 miligram) ; Group 2 :Methotrexate protocol (4 miligram per kilogram) every 14 days intravascular (maximum dose 25 miligram) . Outcome measures: Each cycle of treatment is fourteen days with

measuring the β HCG every two weeks. Once β HCG falls below 5, another three cycles of chemotherapy is done unless there are signs of treatment failure or progression of the disease or unacceptable complications of the medication. Hence in such cases the patients get out the study. Patients are followed by β HCG every month for a year. If the β HCG levels remain high, the patients eventually go through 13 cycles of chemotherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012519567N1**

Registration date: **2015-02-05, 1393/11/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-05, 1393/11/16

Registrant information

Name

Fereshteh Abbaslou

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8825 9354

Email address

mirzalib@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2011-03-21, 1390/01/01
Expected recruitment end date
2015-03-20, 1393/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of pulsed Actinomycin versus 5-day
Methotrexate for the treatment of low-risk gestational
trophoblastic disease in patients

Public title

Comparison of pulsed Actinomycin versus 5-day
Methotrexate for the treatment of low-risk gestational
trophoblastic disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Postmolar Gestational trophoblastic
neoplasm who meet FIGO stage 1,2,3criteria. Patients
must have undergone evacuation of a complete or partial
hydatidiform mole and then meet the criteria : Less than
10% decrease in the β HCG level using as a reference the
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taking as a reference the first value in The series of 3
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of an ectopic pregnancy will be eligible for this study;
Patients with placental site trophoblastic tumor (PSTT) or
epithelioid trophoblastic tumor (ETT); Patients who wish
to breast-feed during treatment; Patients with non-
gestational choriocarcinoma; Disease progression;
Pregnancy.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committe of Tehran University of Medical
Science

Street address

Ghods Street corner, Keshavarz Blvd.Tehran

City

Tehran

Postal code

Approval date

2013-07-27, 1392/05/05

Ethics committee reference number

92/835/130/3

Health conditions studied

1

Description of health condition studied

low risk gestational trophoblastic neoplasm

ICD-10 code

C58

ICD-10 code description

Malignant neoplasms of female genital organs

Primary outcomes

1

Description

BetaHCG test

Timepoint

every 2 weeks

Method of measurement

Assay Kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:Actinomycin pulse protocol(1.25
miligram per square meter)every 14 days intra vascular
(maximum dose 2 miligram)

Category

Treatment - Drugs

2

Description

Intervention group2 :methotrexate protocol (4 miligram perkilogram)every 14 days intravascular (maximum dose25 miligram)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mirza kuchek khan Hospital

Full name of responsible person

Fereshteh Abbaslou

Street address

Shomali Villa Street

City

Tehran

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Fereshteh Abbaslou

Street address

Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Sixth floor, University main building, Ghods corner Street, Keshavarz Blvd.

City

Tehran

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 of Tehran 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

Faculty of medicine,Tehran university

Full name of responsible person

Fereshteh Abbaslou

Position

Gynecology Asistant

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Fereshteh Abbaslou

Position

Gynecology Asistant

Other areas of specialty/work**Street address**

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Fax**Email**

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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