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 MirzaKuchekkhan 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 1,2,3criteria. Patients must have undergone evacuation of a complete or partial hydatidiform mole and then meet the criteria : Less than 10% decrease in the βHCG level using as a reference the first value in the series of 4 values taken over a period of 3weeks ; More than 20% sustained rise in the βHCG taking as a reference the first value in The series of 3 values taken over a period of 2weeks (more than50); Persistently elevated βHCG level a period of 6 months (more than50); 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) ; Group2 :Methotrexate protocol (4 miligram perkilogram)every 14 days intravascular (maximum dose25 miligram) . Outcome measures: Each cycle of treatment is fourteen days with measuring the βHCG every two weeks.Once βHCG falls below5,another three cycles of chemothrapy is done unless there are signs of treatmentfailure 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 βHCG every month for a year.If the βHCG 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

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Fereshteh Abbaslou
Name of organization / entity
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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 βHCG level using as a reference the first value in the series of 4 values taken over a period of 3weeks ; More than 20% sustained rise in the βHCG taking as a reference the first value in The series of 3 values taken over a period of 2weeks (more than50); Persistently elevated βHCG level a period of 6 months (more than50); 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.

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/د

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
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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
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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