

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of Actinomycin D and Methotrexate effectiveness in treatment of Gestational Trophoblastic Neoplasia based on bhCG level

Protocol summary

Summary

The aim of this study is to compare the efficacy of Methotrexate and Actinomycin D as single agents in first-line chemotherapy for women with low-risk gestational trophoblastic neoplasia. A total of 30 women with low-risk gestational trophoblastic neoplasia were randomized to receive a weekly pulsed dose of 40 mg per square meter of body surface of Methotrexate intramuscularly or a pulsed intravenous bolus of 1.25 mg per square meter of body surface of Actinomycin D every 2 weeks. Beta hCG of serum was checked weekly. An additional cycle was administered to both groups as consolidation treatment following normalization of the serum level of beta-human chorionic gonadotropin (less than 10 International Unit per Liter). Duration and number of cycles of chemotherapy and incidence of complication were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012062810128N1**

Registration date: **2012-08-31, 1391/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-31, 1391/06/10

Registrant information

Name

Shima Razi

Name of organization / entity

Jundishapur University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Jundishapur University of Medical Science

Expected recruitment start date

2009-10-01, 1388/07/09

Expected recruitment end date

2011-10-01, 1390/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Actinomycin D and Methotrexate effectiveness in treatment of Gestational Trophoblastic Neoplasia based on bhCG level

Public title

Comparison of Actinomycin D and Methotrexate in treatment of Mole Hydatiform

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patient in OB/GYN clinic of Emam khomeini hospital of ahwaz during 2008 to 2010 suffering low risk gestational trophoblastic neoplasia
exclusion criteria: History of chemotherapy (except for non melanotic skin cancer); History of chemotherapy due to GTN; History of malignancy with less than 5 years disease free; Patient with affected function of liver or kidney

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

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**

Jundishapur University of Medical Science

Street address

Jundishapur University of Medical Science, Golestan Ave, Ahwaz, Khuzestan, Iran

City

Ahwaz

Postal code**Approval date**

2009-09-23, 1388/07/01

Ethics committee reference number

527/3

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

Gestational Trophoblastic Neoplasia

ICD-10 code

O01.9

ICD-10 code description

Mole Hydatiform, Nonspecific Trophoblastic Disease NOS

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

beta hCG

Timepoint

weekly

Method of measurement

mlu/ml

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

liver enzyme elevation

Timepoint

weekly

Method of measurement

mlU/ml

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

Control group: weekly pulsed dose of 40 mg/m(2) of methotrexate intramuscularly

Category

Treatment - Drugs

2**Description**

Intervention group: pulsed intravenous bolus of 1.25 mg per square meter of body surface of Actinomycin D every 2 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomeiny Hospital Ahwaz

Full name of responsible person

Dr.Shima Razi

Street address

Clinic of Gynecologic Oncology of Emam Khomeiny Hospital, Azadegan Ave, Ahwaz, Khuzestan, Iran,

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Jundishapur Medical Science University Branch of Research

Full name of responsible person

Dr Mostafa Fegghi MD

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Jundishapur Medical Science University Branch of Research, Golestan Ave, Ahwaz, Khuzestan, Iran

City
Ahwaz

Grant name

Grant code / Reference number

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

Title of funding source
Jundishapur Medical Science University Branch of Research

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
Jundi Shapur Medical Science University

Full name of responsible person
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Position
Resident of Gynecology

Other areas of specialty/work

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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