

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison effect of single dose of Methotrexate and Actinomycin D in the prevention of gestational trophoblastic neoplasia in patients with high risk hydatidiform mole who refer to Shahid Beheshti and Azahra hospitals of Isfahan university of medical sciences in 2020

Protocol summary

Study aim

Effect of single dose of actinomycin di and methotrexate on prevention of pregnancy trophoblastic neoplasia in high risk molar pregnancies

Design

In this study, 90 patients with high-risk molar pregnancy were randomly divided into three groups of 30 each. The first group received a single dose of actinomycin intravenously, the second group received 50 mg / m² of methotrexate and the third group received a single intramuscular B-ampoule an hour before curettage suction, followed by curettage.

Settings and conduct

This study is carried out during 1399 in Alzahra and Shahid Beheshti hospitals in Isfahan. Patients are randomly assigned to one of the three groups receiving actinomycin, methotrexate and sham at the time of admission to the hospital and, after receiving the intervention, curettage and suctioning is performed on the pineapple. .

Participants/Inclusion and exclusion criteria

In this study, women with complete molar pregnancy who are ready for surgery and termination of pregnancy with suction to discharge molar pregnancy and have at least one risk factor for disease progression to trophoblastic neoplasia of pregnancy are included. Patients who do not have the drugs under study due to problems or medical complications or who are not ready for surgery and termination of pregnancy with suction to discharge the molar pregnancy are not entered in to the study.

Intervention groups

Intervention group 1: Injection single dose of actinomycin D intravenous bolus and then vein wash with 100 ml distilled water one hour before curettage suction
Intervention group 2: Injection 50 mg / m² intramuscular

methotrexate injection one hour before curettage suction
Control group: Injection of intramuscular vitamin B complex as placebo one hour before curettage suction

Main outcome variables

Incidence of gestational trophoblastic neoplasia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N40**

Registration date: **2020-02-25, 1398/12/06**

Registration timing: **prospective**

Last update: **2020-02-25, 1398/12/06**

Update count: **0**

Registration date

2020-02-25, 1398/12/06

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-02, 1399/01/14
Expected recruitment end date
2021-03-18, 1399/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison effect of single dose of Methotrexate and Actinomycin D in the prevention of gestational trophoblastic neoplasia in patients with high risk hydatidiform mole who refer to Shahid Beheshti and Azahra hospitals of Isfahan university of medical sciences in 2020

Public title
omparison effect of single dose of Methotrexate and Actinomycin D in the prevention of gestational trophoblastic neoplasia in patients with high risk hydatidiform mole

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Full molar pregnancy mother age above 40 years old
Patient's consent to participate in the study
Patient Preparation for Surgery and Termination of Pregnancy with Suction for Molar Discharge
Having risk factors for pregnancy progression to trophoblastic neoplasia
Exclusion criteria:
serum level of B-hCG ≥ 100000 iu/ml
theca lutein cyst size ≥ 6 cm

Age
From **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were divided into 3 groups included intervention group1, intervention group 2 and control group by using Random Allocation Software. The total sample size is entered into the software and the number of groups is specified. The software specifies the patients in each group by random number. based on the time of referral, patients will be divided into two groups according to the schedule to reach the required sample size in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description

The study was a double-blind study and patients were unaware of the type of drug being administered. The drug is also prescribed by the researcher, but the data are collected by another specialist physician who is unaware of the type of intervention received.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Research faculty, Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

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Isfahan

Province

Isfahan

Postal code

8434193474

Approval date

2019-12-20, 1398/09/29

Ethics committee reference number

IR.MUI.MED.REC.1398.344

Health conditions studied

1

Description of health condition studied

gestational trophoblastic neoplasia

ICD-10 code

O01.9

ICD-10 code description

gestational trophoblastic neoplasm

Primary outcomes

1

Description

Incidence of gestational trophoblastic neoplasia in Molar pregnancy

Timepoint

Every week for three weeks and the 6 months later

Method of measurement

measurement of beta HCH

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravenous injection of a single dose of actinomycin D and then washing the vein with 10 ml distilled water one hour before suction curettage

Category

Prevention

2

Description

Intervention group: Intramuscular injection of 50 mg methotrexate one hour before curettage suction

Category

Prevention

3

Description

Control group: Intramuscular injection of one ampule B complex one hour before suction curettage

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Samaneh Maghzi

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Alzaha hospital, Soffeh street, Isfahan

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Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Samaneh Maghzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Samaneh Maghzi

Position

Resident of gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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assistant professor

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The project is owned by the state agency and cannot be published

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available