Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of treatment effect of fixed and non-fixed interval prescription of Actinomycin-D on β-HCG level among patients with low-grade gestational trophoblastic neoplasia: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare the treatment effect of fixed and non-fixed interval prescription of Actinomycin-D on β-HCG level among patients with low-grade gestational trophoblastic neoplasia Design: A double blind randomized clinical trial. Setting and conduct: The eligible patients with low-grade gestational trophoblastic neoplasia who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 16 to 50 years; low-grade gestational trophoblastic neoplasia; no response to methotrexate. Exclusion criteria: Pregnancy or breastfeeding; history of herpes or chicken Pox infection; liver or kidney or bone marrow disorder. Intervention group 1: Actinomycin-D 1.25 mg per/square meter every 2 weeks for 3 months. Intervention group 2: Actinomycin-D 1.25 mg per/square meter based on β-HCG level for 3 months. Primary outcome: Measuring the serum level β-HCG before intervention and every week for 1 month and then monthly for 3 months and then every 2 months for 6 months through laboratory test. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706199014N170**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment effect of fixed and non-fixed interval prescription of Actinomycin-D on β-HCG level among patients with low-grade gestational trophoblastic

neoplasia: a double blind randomized clinical trial

Public title
Comparison of treatment effect of fixed and non-fixed interval prescription of Actinomycin-D on β-HCG level among patients with low-grade gestational trophoblastic neoplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age of 16 to 50 years; low-grade gestational trophoblastic neoplasia; no response to methotrexate. Exclusion criteria: Pregnancy or breastfeeding; history of herpes or chicken Pox infection; liver or kidney or bone marrow disorder.
Age
From **16 years** old to **50 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code

Approval date
2017-06-10, 1396/03/20
Ethics committee reference number
IR.UMSHA.REC.1396.253

Health conditions studied

1

Description of health condition studied
Trophoblastic neoplasia
ICD-10 code
O01.9
ICD-10 code description
Hydatidiform mole, unspecified

Primary outcomes

1

Description
Measuring the serum level β-HCG
Timepoint
before intervention and every week for 1 month and then monthly for 3 months and then every 2 months for 6 months
Method of measurement
through laboratory test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Actinomycin-D 1.25 mg per/square meter every 2 weeks for 3 months.
Category
Treatment - Drugs

2

Description
Intervention group 2: Actinomycin-D 1.25 mg per/square meter based on β-HCG level for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Somayeh Heidari
Street address
Fatemieh Hospital, Pasdaran Ave.

City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
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 and Technology, Hamadan 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
Fatemieh Hospital
Full name of responsible person
Dr Somayeh Heidari
Position
Resident of Gynecology
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
drsrezvan@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fatemieh Hospital
Full name of responsible person
Dr Mehrangiz Zamani
Position
Gynecologist
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
m.zamani@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.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