

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of methotrexate and actinomycin D in the treatment of patients with C-section ectopic pregnancy

Protocol summary

Registration timing: **prospective**

Study aim

The aim of this study is to investigate and compare the effect of methotrexate and actinomycin D on patients with cesarean scar ectopic pregnancy, due to less side effects, more accessibility and less costs in the treatment by Actinomycin-D as a chemotherapy agent that has side effects similar to methotrexate without central nervous system's side effects.

Design

Two arm parallel group, double-blind, randomized, phase 3 clinical trial on 32 patients. Lottery method used for randomization.

Settings and conduct

Eligible patients who referred to Hazrat Rasool Akram and Firozgar Hospital in Tehran were assigned to two groups, the first group received methotrexate and the second group Actinomycin D. Then, BHCG levels are recorded. If there is any complication, drop in hemoglobin or no reduction in BHCG, the intervention will be discontinued and resection of the mass will be performed by surgical intervention.

Participants/Inclusion and exclusion criteria

32 patients with C-section ectopic pregnancy will enrolled. Patients with vaginal bleeding and hemodynamic instability will be excluded.

Intervention groups

First group will receive actinomycin D and the second methotrexate.

Main outcome variables

level of the blood chorionic gonadotropin hormone (BHCG)

Last update: **2023-04-04, 1402/01/15**

Update count: **0**

Registration date

2023-04-04, 1402/01/15

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 23 3343 7844

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of methotrexate and actinomycin D in the treatment of patients with C-section ectopic pregnancy

Public title

Assessing the effectiveness of methotrexate and actinomycin D in the treatment of patients with C-section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N16**

Registration date: **2023-04-04, 1402/01/15**

ectopic pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of -section ectopic pregnancy
Exclusion criteria:
Gestational age more than 13 weeks at the time of diagnosis Heavy vaginal bleeding Hemodynamic changes

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: 32

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, at first stage, 32 spheres from one to 32 are considered and following that will randomly divided into two equal parts, including "1" (Intervention1) and group 2 (Intervention2), and then using a lottery container, the ball of each group taken out and the intended sequence will be recorded.

Blinding (investigator's opinion)
Double blinded

Blinding description
The blinding of the study is such that the care provider, outcome assessor and biostatistician do not know the content of the intervention. For administration, the drug is drawn by the researcher into the syringe and given to the clinical care provider for administration by mentioning the administration method. The outcome assessor records the outcome based on the patient's identity number according to the randomization table, and the data collected based on the number and mention of the first and second intervention is provided to the biostatistician for analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee, Iran University of Medical Sciences

Street address
Hemmat Expressway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2022-08-06, 1401/05/15

Ethics committee reference number
IR.IUMS.FMD.REC.1401.269

Health conditions studied

1

Description of health condition studied
C-Section Ectopic Pregnancy

ICD-10 code
O00.9

ICD-10 code description
Ectopic pregnancy, unspecified

Primary outcomes

1

Description
Level of the blood chorionic gonadotropin hormone (BHCG)

Timepoint
4, 7, 14 and 21 days after intervention

Method of measurement
Enzyme-Linked Immunesorbent Assay (ELIZA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Methotrexate is given as a single dose of 50 mg by intramuscular injection. This dose is repeated after 14 days if there is no therapeutic result.

Category
Treatment - Drugs

2

Description
Intervention group: Actinomycin D is given as a single dose of 0.5 mg by intravenous infusion. This dose is repeated after 14 days if there is no therapeutic result.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasool Akram hospital
Full name of responsible person
Soodabeh Jamali
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2

Recruitment center

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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr. Setareh Nasiri Zeidi
Position
Assistant Professor
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The data collection will be presented anonymously.
When the data will become available and for how long
After publishing of the results, the data will be delivered upon request and after verification.
To whom data/document is available
The data will be available only for academic researchers.
Under which criteria data/document could be used
In order to conduct similar studies.
From where data/document is obtainable
Direct request from the scientific responsible.
What processes are involved for a request to access data/document
After request and authentication, the data will be provided.
Comments