Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of chemotherapy on anti-mullerian hormone levels in patients with GTN

Protocol summary

Summary
Ovary is one of the target tissue during chemotherapy, which destroyed the primordial follicles and eventually cause ovarian failure. To assess the impact of chemotherapy on ovarian reserve in patients with gestational trophoblastic neoplasia (GTN), we evaluated the post-chemotherapy serum anti mullerian hormone (AMH) levels. This is a non-randomized interventional study with out blinded. 70 patients between the ages of 18-45 years old who confirmed the molar pregnancy by pathology included in this study and then according to decrease of BhCG titrage, devide in 2 groups with 35 patients. The control group including patients in which weekly follow-up of BhCG titrage reaches zero and the case group including patients that require chemotherapy base on GTN criteria. Anti-Mullerian hormone levels as a marker to detect ovarian reserve measured once before suction-curttage then after BhCG titrage becomes zero. Finally the average of AMH in both groups are compared.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201104165810N2**
Registration date: **2017-05-09, 1396/02/19**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2017-05-09, 1396/02/19

Registrant information
Name
Nazanin Atrvash
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Hamedan university of Medical science
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Recruitment status
Recruitment complete
Funding source
private

Expected recruitment start date
2014-01-21, 1392/11/01
Expected recruitment end date
2016-11-21, 1395/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of chemotherapy on anti-mullerian hormone levels in patients with GTN

Public title
The impact of chemotherapy on ovarian reserve in patients with molar pregnancy
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria: Patient between the ages of 18-45 years who confirmed the molar pregnancy with pathology exclusion criteria: 1- Endocrine diseases 2- History of ovarian surgery
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan University of Medical Science
Street address
Ethics committee, Hamedan University of Medical Science, Pazhohesh Boulevard, Hamedan
City
Hamedan
Postal code
Approval date
2017-02-18, 1395/11/30
Ethics committee reference number
IR.UMSHA.REC.1395.565

Health conditions studied

1

Description of health condition studied
Hydatidiform mole
ICD-10 code
Neoplasms
ICD-10 code description
Neoplasm of uncertain or unknown behaviour: Placenta

2

Description of health condition studied
molar pregnancy
ICD-10 code
Pregnancy,
ICD-10 code description
Hydatidiform mole, unspecified

Primary outcomes

1

Description
Anti mullerian hormone
Timepoint
before suction curttage- after zero beta titrage
Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: suction curettage, prescription of chemotherapy drugs. Based on the patient's condition, we used MTX or ACD or a combination of both. MTX dosage was 1mg/kg and administered every 3 weeks intra-musculary. ACD dosage was 1 mg/m2 and administered every 2 weeks intra musculary. Repeat doses based on patients response to therapy.
Category
Diagnosis

2

Description
Intervention group 2: Suction Curettage
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Nazanin Atrvash
Street address
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Private
Full name of responsible person
Nazanin Atrvash
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Kermanshah st, Fatemieh Hospital
City

Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Private
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

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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