Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Role of hysteroscopy in management of persistent mole

Protocol summary

Summary

Gestational trophoblastic tumor of pregnancy consist of a group of disorders like complete and partial, invasive mole and placental site tumor and choriocarcinoma. All of them have different tendency for invasion and metastasis. This is a specific tumor of reproductive age and most of patients are under 35 years old. The incidence of molar pregnancy in Asia is 7-10 times more than United States and Europe. Regarding of this reproductive age disorder sometimes hysterectomy is necessary for cure which leads to sterility. However timed diagnosis and treatment leads to 90% percent complete recovery All patients who had history of D&C and molar pregnancy at pathologic report and the level of B-hCG is plateau or rising and they are referred for chemotherapy , are recruited in this trial. All of them will undergo under hysteroscopic resection of molar residue and then the B-hcg levels, TVS and pathologic reports will be evaluated. If the B-hCG is negative chemotherapy will be cancelled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601222576N11**
Registration date: **2016-08-26, 1395/06/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-26, 1395/06/05

Registrant information

Name
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Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2016-02-02, 1394/11/13

Expected recruitment end date
2018-02-12, 1396/11/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Role of hysteroscopy in management of persistent mole

Public title
Role of hysteroscopy in management of persistent mole

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with persistent mole(residual of pregnancy in trans vaginal sonography and positive hCG after D&C) are recruited in the study.
Exclusion criterion: patients who prefer chemotherapy instead of hysteroscopy.

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: **30**

Randomization (investigator's opinion)

N/A

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

Ethic Commitee of Tehran University of Medical Sciences

Street address

Fifth floor, Central building of TUMS, Ghods Avenue, Keshavarz Boulvard

City

Tehran

Postal code

Approval date

2016-01-20, 1394/10/30

Ethics committee reference number

IR.TUMS.REC.1395.2799

Health conditions studied

1

Description of health condition studied

Molar Pregnancy

ICD-10 code

O01.9

ICD-10 code description

Hydatidiform mole, unspecified

Primary outcomes

1

Description

B-hCG levels decrease

Timepoint

After one week

Method of measurement

ml/Unit/ml

Secondary outcomes

1

Description

No residuea of pregnancy after hysteroscopy

Timepoint

After one week

Method of measurement

Trans vaginal sonography

Intervention groups

1

Description

Intervention: Hysteroscopic resection of molar tissues in 30 patients

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Women Hospital of Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy Research of Tehran University of Medical Sciences

Full name of responsible person

Mis Hajar Moamaei

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Fifth floor- Central building of TUMS, Ghods Avenue, Keshavarz Boulvard

City

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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

Deputy Research of Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

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Position

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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