

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Fatemeh Davari Tanha

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8831 3955

##### Email address

fdavaritanha@sina.tums.ac.ir

##### 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 Committee of Tehran University of Medical Sciences

##### Street address

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

##### 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

##### Street address

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

##### City

Tehran

##### 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*

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## Person responsible for general inquiries

### Contact

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Tehran University of Medical Sciences  
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Fatemeh Davari Tanha  
**Position**  
Associate professor of TUMS  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*