

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparison of the effects of treatment with premarine and clobetasol - premarin in vaginal involvement of GVHD (Graft-versus-host disease) after hematopoietic stem cell transplantation

#### Protocol summary

transplant-induced GVHD

##### Study aim

Determining the effects of treatment with premarin and clobetasol-premarin in the vaginal involvement of graft-versus-host disease (transplant-induced GVHD)

##### Design

Randomized Clinical trial, with parallel groups, randomized, on 55, which is used for randomization of double blocks.

##### Settings and conduct

Patients referred to Shariati Hospital in Tehran who underwent bone marrow transplantation. After identifying the patients, the rate of response to steroid and premarin treatment is evaluated. Also, clinical symptoms such as vaginal dryness, burning sensation during urination, pelvic pain, vulva ulcer, vaginal discharge, vaginal inflammation, scar in the clitoris, vaginal shortening, vaginal tightness, vaginal closure (as well as complications due to transplantation, duration The occurrence of GVHD after transplantation, the prevalence of vaginal GVHD) is also recorded. The type of transplanted cells (allogeneic or autologous) is also investigated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who receive a bone marrow cell transplant; have no disease in the genital area before transplantation; have genital involvement including vaginal involvement after bone marrow transplantation; those who have informed consent to participate in the study. Exclusion criteria: patients without informed consent or death during the study.

##### Intervention groups

In the first group, Peremarin cream is used once a day along with the mold, and in the second group, clobetasol-premarin combined treatment is used every other day (for 6 weeks).

##### Main outcome variables

Vaginal involvement of graft-versus-host disease

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160615028486N3**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

##### Registration date

2022-07-27, 1401/05/05

##### Registrant information

##### Name

Mansooreh Yaraghi

##### Name of organization / entity

Tehran University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8828 0618

##### Email address

dr\_m\_yaraghi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-27, 1401/05/05

##### Expected recruitment end date

2022-09-09, 1401/06/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effects of treatment with premarine and clobetasol - premarin in vaginal involvement of GVHD (Graft-versus-host disease) after hematopoietic stem cell transplantation

**Public title**  
Effects of treatment with premarin and clobetasol-premarin in vaginal disease after hematopoietic stem cell transplantation.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Female patients undergoing bone marrow transplantation Consent to participate in research  
**Exclusion criteria:**  
History of cervical cancer History of uterine,cervical,vaginal congenital anomaly Patient disagreement

**Age**  
From **18 years** old to **80 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **55**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization is done by the method of 4 blocks. Patients are assigned to each treatment group in a ratio of 2 : 2.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

6th floor, Centar building of Tehran University of Medical Sciences, Ghods Street, Keshavarz Blvd.

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Approval date

2022-03-16, 1400/12/25

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1505

## Health conditions studied

### 1

#### Description of health condition studied

Graft-versus-host disease (GVHD)

#### ICD-10 code

D89.81

#### ICD-10 code description

Graft-versus-host disease

### 2

#### Description of health condition studied

Hematopoietic stem cell transplantation

#### ICD-10 code

T86.5

#### ICD-10 code description

Complications of stem cell transplant

## Primary outcomes

### 1

#### Description

Vaginal involvement of graft-versus-host disease

#### Timepoint

1 year

#### Method of measurement

Gynecology examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Premarin cream is used once a day along with the mold for 6 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Clobetasol-premarin combined

treatment is used every other day (for 6 weeks).

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shariati Hospital Gynecology

**Full name of responsible person**

Mansooreh Yaraghi

**Street address**

North Kargarst., Jalal Al-Ahmad St.

**City**

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**Province**

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**Postal code**

1411713135

**Phone**

+98 21 8490 1000

**Fax**

+98 21 8863 3039

**Email**

Dr\_m\_yaraghi@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Akbar Fotouhi

**Street address**

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

**City**

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**Postal code**

14117 13135

**Phone**

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+98 21 8163 3698

**Email**

vcr@tums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mansooreh Yaraghi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Email**

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**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**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Demographic characteristic of patient and main study result

**When the data will become available and for how long**

Three months after publication of result

**To whom data/document is available**

All people who work in this field

**Under which criteria data/document could be used**

every time

**From where data/document is obtainable**

Mansooreh Yaraghi dr\_m\_yaraghi@yahoo.com

**What processes are involved for a request to access data/document**

Send an e-mail to Mansooreh Yaraghi

**Comments**