Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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

Main outcome variables
Vaginal involvement of graft-versus-host disease transplant-induced GVHD

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: Clobetazol-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

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North Kargarst., Jalal Al-Ahmad St.

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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

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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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Latest degree
Specialist
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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 mounts 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