Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment of the efficacy and safety of combined mouthwash containing cyclosporine, dexamethasone, and nystatin in treating chronic mucosal graft-versus-host disease in patients undergoing hematopoietic stem cell transplantation: a clinical trial

Protocol summary

Study aim

This study evaluates the safety and efficacy of a novel mouthwash containing cyclosporine, dexamethasone, and nystatin in patients with oral cGvHD. The formulation may improve oral lesions, reduce symptoms, enhance quality of life, and prevent fungal infections.

Design

The present clinical trial is a single group, phase 3, that will be conducted on 20 patients.

Settings and conduct

This study is conducted at the Oncology, Hematology, and Cell Therapy Research Center located at Shariati Hospital. Twenty patients are enrolled in the study, and their conditions are monitored and evaluated over six consecutive weeks.

Participants/Inclusion and exclusion criteria

Exclusion criteria: Patients with hypersensitivity to any formulation component (cyclosporine, dexamethasone, or nystatin); concurrent systemic tacrolimus use; active acute oral bacterial, viral, or fungal infection; pregnancy or breastfeeding; acute adverse events requiring discontinuation of calcineurin inhibitors; poor cooperation during follow-up; non-compliance with proper mouthwash use or storage (e.g., incorrect dosing, discontinuation, or swallowing after topical use); or use of topical oral corticosteroids within the past 12 weeks.

Intervention groups

Age over 18 years History of hematopoietic stem cell transplantation (HSCT) more than 100 days prior Evidence of chronic GvHD Clinically symptomatic erosive and ulcerative cGvHD as confirmed by the treating physician Inadequate response to initial systemic therapy (corticosteroid or calcineurin inhibitor) within the past 4 weeks Patient’s informed consent to participate in the study

Main outcome variables

Improvement of oral lesions caused by chronic mucosal GvHD

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N52**
Registration date: **2026-06-29, 1405/04/08**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-29, 1405/04/08**
Update count: **0**

Registration date

2026-06-29, 1405/04/08

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation,Tehran University of Medic

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-26, 1405/04/05

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the efficacy and safety of combined mouthwash containing cyclosporine, dexamethasone, and nystatin in treating chronic mucosal graft-versus-host disease in patients undergoing hematopoietic stem cell transplantation: a clinical trial

Public title
Assessment of the efficacy and safety of combined mouthwash containing cyclosporine, dexamethasone, and nystatin in treating chronic mucosal graft-versus-host disease in patients undergoing hematopoietic stem cell transplantation: a clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Over 18 years old It has been over 100 days since the hematopoietic stem cell transplantation Chronic graft-versus-host disease (GVHD) evidence Clinical diagnosis of symptomatic erosive chronic graft-versus-host-disease (cGvHD) based on the treating physician,s assessment Informed consent of the patient for participation in the study

Exclusion criteria:
History of allergy to any of the excipients in the formulation including cyclosporine, dexamethasone and nystatin Simultaneous administration of systemic tacrolimus The presence of acute bacterial, viral or fungal oral infection Pregnancy or breastfeeding The occurrence of acute adverse effects leading to discontinuation of calcineurin inhibitors Non compliance with follow-up stages Patient,s non-adherence to proper medication usage or maintenance History of receiving topical oral corticosteroids within the past 12 weeks Simultaneous receipt of phototherapy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
Research Ethics Committee of the Pharmaceutical Sciences Research Center, Tehran University of Medic

Street address
Pour Sina St, District 6, Tehran, Tehran Province

City
Tehran

Province
Tehran

Postal code
Tehran, Enghelab Squ

Approval date
2024-10-30, 1403/08/09

Ethics committee reference number
IR.TUMS.TIPS.REC.1403.146

Health conditions studied

1

Description of health condition studied
Chronic mucosal graft-versus-host disease (GVHD)

ICD-10 code
D89.811

ICD-10 code description
Chronic graft-versus-host disease

Primary outcomes

1

Description
The severity of oral symptoms, including pain, burning, and dryness (based on VAS), and the severity of oral involvement due to cGVHD (based on the NIH oral score).

Timepoint
6 weeks

Method of measurement
Clinical evaluation- ٧AS - NIH Oral score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The mouthwash will be administered topically, twice daily, 10 cc each time, for a duration of 1 to 5 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr Bita Shahrami

Street address

آدرس خیابان Kargar Shomali Ave, Shariati Hospital, Tehran

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1411713135

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Bita.Shahrami@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

دکتر بیتا شهرامی

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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

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

مریم برخوردار

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for scientific 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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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Leyla sharifi Aliabadi

Position
Research Assistant

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available