

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Evaluating the effects of a combined product of Sodium Hyaluronate, Glycine, L-Proline, L-Leucine, L-Lysine in preventing the occurrence of Oral Mucositis in pediatric Hematopoietic Stem Cell Transplant patients

Protocol summary

Study aim

To evaluate the effects of topical mucosamine spray in preventing the development of oral mucositis in pediatric hematopoietic stem cell transplant recipients

Design

Two arms, parallel group design of 60 patients, placebo controlled, double blind randomized clinical trial, phase three, single center

Settings and conduct

In this research, the effects of mucosamine spray in preventing the Oral mucositis in pediatric Hematopoietic Stem Cell Transplantation (HSCT) patients will be evaluated, 60 pediatric patient, admitted to HSCT ward of the Shariatee hospital of the Tehran University of Medical Sciences will be enrolled and randomized to placebo or treatment groups using a random number table. Patients in intervention group will receive mucosamine topical spray 4 times per day for 14 days 7 days before till 7 days after receiving stem cells whereas, patients in placebo group will receive topical placebo spray. The study is designed as a double blind randomized trial, and the researcher, nurses and patients will not be aware of the product ingredients. Products will be delivered to the researcher in similar, encoded and labeled containers by product provider and safety board of the study. The severity of the oral mucositis will be evaluated by NCI-CTCEA v5 criteria.

Participants/Inclusion and exclusion criteria

- Inclusion criteria: age less than 18 years undergoing allogeneic hematopoietic stem cell transplantation - Exclusion criteria: active mucositis at the time of admission history of hypersensitivity reactions to mucosamine or any of its ingredients diagnosis of fanconi's anemia

Intervention groups

Patients in intervention group will receive mucosamine topical spray and patients in placebo group will receive topical placebo spray 4 times a day 7 days before and 7

days after receiving stem cell transplantation

Main outcome variables

Severity of oral mucositis Incidence of oral mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044805N1**

Registration date: **2019-12-05, 1398/09/14**

Registration timing: **prospective**

Last update: **2019-12-05, 1398/09/14**

Update count: **0**

Registration date

2019-12-05, 1398/09/14

Registrant information

Name

Kourosh Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

sadeghi_k@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of a combined product of Sodium Hyaluronate, Glycine, L-Proline, L-Leucine, L-Lysine in preventing the occurrence of Oral Mucositis in pediatric Hematopoietic Stem Cell Transplant patients

Public title

Evaluating effects of Sodium Hyaluronate and four amino acids in oral mucositis prevention

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age below 18 years old Undergoing allogenic hematopoietic stem cell transplantation

Exclusion criteria:

Patients with active oral mucositis at the time of admission History of hypersensitivity reactions to mucosamine spray or any of its ingredients Patients with the diagnosis of fanconie's anemia

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization method will be used to randomize patients to blocks of four, using an random number table which was built by a computer software by the statistic's expert will be utilized to randomly assign the patients to placebo or medication groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding procedure is carried out using a random number table, which is going to be provided by statistics expert, each number of the table is going to be assigned to a specific patient and the researcher, nurses and patients are not going to be aware of the product ingredients. Only product provider and safety board of the study would know which product contains drug or placebo. The researcher will receive the products in sealed and labeled containers and randomly deliver them to patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic's committee of tehran university of medical sciences

Street address

16th azar street

City

Tehran

Province

Tehran

Postal code

14176141141

Approval date

2019-09-03, 1398/06/12

Ethics committee reference number

IR.TUMS.TIPS.REC.1398.077

Health conditions studied**1****Description of health condition studied**

oral mucositis

ICD-10 code

K12.30

ICD-10 code description

Oral mucositis (ulcerative), unspecified

Primary outcomes**1****Description**

oral mucositis severity

Timepoint

every other day, since the day of admission till the day of discharge

Method of measurement

National Cancer Institute Common Terminology of Adverse Events criteria version 5

Secondary outcomes**1****Description**

Mucositis incidence

Timepoint

Every other day

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: patients in this group will receive topical mucosamine spray manufactured by Professional Dietetics Italy, four times daily 7 days before receipt of hematopoietic stem cells till 7 days after transfusion of hematopoietic stem cells. the topical spray contains Sodium Hyaluronate, Glycine, L-Proline, L-Leucine and L-Lysine.

Category

Prevention

2

Description

Control group: the patients in control group will receive the placebo product containing all the ingredients of medication product but with out Sodium Hyaluronate, Glycine, L-Proline, L-Leucine and L-Lysine, four times daily 7 days before receipt of hematopoietic stem cells till 7 days after transfusion of hematopoietic stem cells.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

hematology-oncology and stem cell transplantation research center of Shariati hospital of Tehran Uni

Full name of responsible person

Kurosh sadeghi

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16th azar street

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Email

sadeghi_k@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

kurosh sadeghi

Street address

16th azar street

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Tehran

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Phone

+98 21 8490 1000

Email

sadeghi_k@tums.ac.ir

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

kurosh sadeghi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPDit is the study policy to keep patient information secret
as agreed in informed consent note**Study Protocol**

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data DictionaryUndecided - It is not yet known if there will be a plan to
make this available**Title and more details about the data/document**data regarding primary and secondary outcomes and
demographic variables will be shared**When the data will become available and for how long**data will be available following study termination and is
expected to be available online January 2021**To whom data/document is available**

to medical practitioners

Under which criteria data/document could be useddata could be used after proper permissions are granted
by the researchers**From where data/document is obtainable**

Tehran University of Medical Sciences

What processes are involved for a request to access data/documenta written note should be provided by the person in order
to obtain data**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

kurosh sadeghi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

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