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 hematopeitic stem cell transplant recipients

Design
Two arms, parallel group deign 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 Hematopeitic 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 allogenic hematopeitic stem cell transplantion - 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
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Iran (Islamic Republic of)
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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 hematopeitic 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 ingreedients 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 hematopeitic stem cells till 7 days after transfusion of hematopeitic 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 hematopeitic stem cells till 7 days after transfusion of hematopeitic 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
kurosh sadeghi
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Phone
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Email
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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
kurosh sadeghi
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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assistant professor
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Person responsible for updating data

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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 IPD
it 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 Dictionary
Undecided - 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
datat 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 used
data 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/document
a written note should be provided by the person in order to obtain data
Comments