

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of effects of topical solution of vitamin E in preventing oral mucositis in Allogenic Hematopoietic Stem Cell Transplantation patients

Protocol summary

Study aim

The aim of the current study is to find a new way to prevent the occurrence of mucositis and decrease its severity in recipients of hematopoietic stem cell transplant who receive conditioning regimen with the combination of Busulfan and Cyclophosphamide.

Design

Two arm parallel, randomized double blind placebo controlled clinical trial

Settings and conduct

This study is going to take place in Bone Marrow Transplantation center of Tehran. Patients included in this study are supposed to receive a topical solution that contains Vitamin E or placebo, twice daily and be evaluated each day by the researcher in order to examine the effects of topical vitamin E on the occurrence and severity of the oral mucositis. Preparation of the topical solution is going to be done by department of Pharmaceutics in Faculty of Pharmacy. The chief of research and Pharmaceutics expert will be the only ones aware of the formulation content and will make proper decisions based on the circumstances.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age more than 18 years - Receiving conditioning regimen with Busulfan and Cyclophosphamide
Exclusion criteria: - Patients with active mucositis at the time of admission - Active bleeding - Any contraindications to vitamin E, including history of hypersensitivity reactions to drug or any component of the formulation

Intervention groups

In this study, patients are going to be divided into two groups. patients in the test group will receive a topical solution that contains vitamin E 400 IU twice daily and are supposed to rinse their mouth with the solution and spit it out. The patients in the placebo group are going to receive an identical looking solution that does not contain vitamin E.

Main outcome variables

- Decreased incidence and severity of oral mucositis -
Decreased need for narcotic pain killers - Decreased length of ward stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039325N1**

Registration date: **2018-07-25, 1397/05/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-25, 1397/05/03**

Update count: **0**

Registration date

2018-07-25, 1397/05/03

Registrant information

Name

Mohammad Solduzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 6218

Email address

M-solduzian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of effects of topical solution of vitamin E in preventing oral mucositis in Allogenic Hematopoietic Stem Cell Transplantation patients

Public title
Effects of topical vitamin E solution in mucositis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age older than 18 years Receiving conditioning regimen with Busulfan and Cyclophosphamide
Exclusion criteria:
Showing active mucositis signs and symptoms at the time of admission Active bleeding Any contraindication to vitamin E as hypersensitivity reactions

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients are going to be divided into blocks of 8 patients. For randomization a random numbers table is going to be utilized. Patients who will receive the odd numbers are going to be given the product labeled as number 1 and patients who will receive the even numbers are going to be given the product labeled as number 2. Allocation concealment is carried out by blinding the researcher.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the current study, the pharmaceutical products containing drug or placebo are going to be formulated in Tehran University of Medical Sciences, Faculty of Pharmacy and delivered to the researcher. Neither the patient, attending nurse or researcher are going to be aware of which product contains the drug. The head of the clinical trial and pharmaceuticals expert will be aware of the patients status including which one receives the drug or placebo and will make proper decisions to proceed with the trial or discontinue it based on situation and inform the related authorities.

Placebo
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
North Kargar st, Jalal st, Sahriaty Hospital, Hematology- Oncology and Bone Marrow Transplant Center,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1411713135
Approval date
2018-05-06, 1397/02/16
Ethics committee reference number
IR.TUMS.TIPS.REC.1397.017

Health conditions studied

1

Description of health condition studied
Oral mucositis
ICD-10 code
K12.3
ICD-10 code description
Oral mucositis (ulcerative)

Primary outcomes

1

Description
Incidence of oral mucositis
Timepoint
Daily for 15 days which is the duration that patient receives the formulation
Method of measurement
Clinical evaluation based on National Cancer Institute Common Terminology Criteria for Adverse Effects version 4.0 scale

2

Description
Severity of oral mucositis
Timepoint
Daily for 15 days which is the duration that patient receives the formulation

Method of measurement

Clinical evaluation based on National Cancer Institute
Common Terminology Criteria for Adverse Effects version
4.0 scale

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

Duration of Bone Marrow Transplant ward stay

Timepoint

From the day of admission to Bone Marrow Transplant
ward until discharge form the ward

Method of measurement

Medical records

2**Description**

The need for narcotic analgesic

Timepoint

From the day of admission to Bone Marrow Transplant
ward until discharge form the ward

Method of measurement

Medical records

Intervention groups**1****Description**

Intervention group: Patients in the intervention group are
supposed to receive vitamin E mouth wash solution, that
contain 400 IU of the drug in each dose, twice daily and
be evaluated daily by the researcher in order to find the
effects of vitamin E on the incidence and severity of oral
mucositis. The mouth wash solution contains glycerin,
sodium chloride, sodium benzoate and polysorbate 20 in
water base.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

shariaty hospital

Full name of responsible person

Moluk Haji Babayi

Street address

North Kargar st, Jalal AL Ahmad st, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

m-solduzian@razi.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Moluk Haji Babayi

Street address

North Kargar st, Jalal st, Sahriaty Hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

m-solduzian@razi.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

Moluk Haji Babayi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

North Kargar st, Jalal st, Sahriaty Hospital, Tehran

City

Tehran

Province

Tehran

Postal code
1411713135
Phone
+98 21 8490 1000
Email
m-solduzian@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Moluk Haji Babayi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
North Kargar st, Jalal st, Sahriaty Hospital, Tehran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
m-solduzian@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Solduzian
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
North Kargar st, Jalal Al Ahmad st, Tehran
City
Tehran
Province

Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
m-solduzian@razi.tums.ac.ir

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

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

Not applicable

Title and more details about the data/document

Evaluation of effects of topical solution of vitamin E in preventing oral mucositis in allogenic Hematopoietic Stem Cell Transplantation patients.

When the data will become available and for how long

the data of the study is anticipated to be available in 6/15/2019 and be available indefinitely

To whom data/document is available

the plan is to publish the results of the research in valid data bases and make available for fellow researchers from different fields

Under which criteria data/document could be used

the private data that belongs to patients is not going to be available to anyone and different analysis could be performed on the provided data under proper referencing rules.

From where data/document is obtainable

publishable data or documents could be obtained by contacting through the following routes: - email: m-solduzian@razi.tums.ac.ir - phone number: 00989120920355

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

the request should be submitted to above mentioned e.mail or phone number, and the required information must be verified by the chief of research, then the data will be available only if ethic committee proves it is publishable.

Comments