

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of Oral Cryotherapy and Normal Saline Mouth Rinse on Chemotherapy -Induced Oral Mucositis in Patients with Autologous Blood Stem-Cell Transplantation: A Randomized clinical Trial

Protocol summary

Summary

This clinical trial study will perform for determining the effect of ice chips and Normal Saline mouth rinse on oral mucositis in patients with autologous blood Stem-Cell transplantation, after approval and ethics committee's confirmation. Participants include patients with multiple myeloma, Hodgkin and non Hodgkin lymphoma which will be chosen by convenience sampling based on inclusion criteria and will be allocated to two groups randomly. One group by cryotherapy and the other by Normal saline will have mouth care. At first, the demographic form of participants will be filled by the researcher. During first chemotherapy process, in intervention group (ice-therapy) the ice chips will place in the mouth by the nurse, from 5 minutes before, during and 5 minutes after each administration of chemotherapy period continuously (mean time 20-40 Min) with considering his tolerance and with 20 minutes interval resting. The ice therapy will continue based on chemotherapy protocol. In both groups the usual oral care will continue during study. For determining the severity of mucositis, before intervention, third day after chemotherapy process, moreover every week until 3 weeks after chemotherapy period, WHO mucositis Scale will be filled by the researcher in both groups in 5 degree (0-4) then demographic data and WHO scale will compare and analyze by statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307165665N4**
Registration date: **2013-10-15, 1392/07/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-15, 1392/07/23

Registrant information

Name

Sima Lakdizaji

Name of organization / entity

Tabriz University of Medical Sciences, Nursing and Midwifery Faculty

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences - Nursing and Midwifery Faculty- Vice chancellor for research

Expected recruitment start date

2013-10-06, 1392/07/14

Expected recruitment end date

2014-04-06, 1393/01/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Oral Cryotherapy and Normal Saline Mouth Rinse on Chemotherapy -Induced Oral Mucositis in Patients with Autologous Blood Stem-Cell Transplantation: A Randomized clinical Trial

Public title

Effect of Oral Cryotherapy and Normal Saline Mouth Rinse on Chemotherapy -Induced Oral Mucositis in Patients with Blood Stem-Cell Transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Consciousness; Age between 18 to 70 years; To have Hodgkin's, non Hodgkin's lymphoma or Multiple Myeloma with the same grades; To have healthy oral mucous; Isolation of participants from the beginning of the project; To have Similar Chemotherapy properties; To have the same Autologous transplantation protocols
Exclusion criteria: Participants' dissatisfaction; Loss of consciousness; Suffering from other diseases during treatment; use of narcotic analgesics continuously before the study; Combined therapies such as radiation therapy at the time of study; Fever, neutropenia and mucositis before starting treatment; To have respiratory diseases such as asthma and oral infections; Systemic diseases effective on oral tissues, especially periodontal disease; To have chemotherapy two weeks before transplantation; Change in treatment protocol during the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

The ethics committee of Tabriz University of Medical Sciences

Street address

Research Deputy- Amoozesh building- Tabriz University of Medical Sciences- Daneshgah Ave.- Tabriz

City

Tabriz

Postal code**Approval date**

2013-09-17, 1392/06/26

Ethics committee reference number

9299

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**

Oral Mucositis

Timepoint

before chemotherapy and 3rd, 7th, 14th and 21th days following end of chemotherapy

Method of measurement

WHO Mucositis Scale

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

Nausea and Vomiting

Timepoint

During 4 days, every day following end of chemotherapy

Method of measurement

checklist

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

In intervention group (ice-therapy) the small ice pieces will prepare in plastic freezer disposable formats (casts) with ready clean mineral water in dedicated refrigerator of each patient. During chemotherapy process, for cooling the oral cavity, the ice chips will place in mouth by the nurse, from 5 minutes before, during and 5 minutes after each intravenous administration of chemotherapy period continuously (mean time 20-40 Min) with considering his tolerance and with 20 minutes interval resting. The ice therapy maintains will continue based chemotherapy protocol. As the ice pieces melts it will replace with new ones. The ice pieces will prepare in a manner that would not irritate the oral cavity and could easily move in the mouth (size approximately 3*4 cm

casts) will be provided in sterile containers to patients. If the participants have the prosthetic teeth, they will be asked to remove it. The usual oral care will continue after stem cell transplantation.

Category

Prevention

2**Description**

In saline rinse group, the participants will be asked to rinse their mouth by a saline solution with the room temperature (23-29 centigrade degree), 30 minutes before chemotherapy to 6 hours after it, every 30 minutes by the nurse. In this way 30-50 ml of normal saline will be used in every time. The usual oral care will continue after transplantation of stem cells.

Category

Prevention

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

Namazi transplantation hospital affiliate to Shiraz Medical science University

Full name of responsible person

Marzie Askarifar

Street address**City**

Shiraz

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

Nursing and Midwifery Faculty- Vice chancellor for research

Full name of responsible person

Sima Lakdizaji

Street address

Nursing and Midwifery Faculty- Shariati Jnoobi Ave- Tabriz

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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

Nursing and Midwifery Faculty- Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Marzieh Askarifar

Position

MSc in Nursing

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Lecturer- Master Science(MSc in Nursing)

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty