

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of sodium bicarbonate and zinc chloride mouth washes on incidence and severity of oral mucositis in patients with cancer under chemotherapy

Protocol summary

Study aim

Comparison the effect of sodium bicarbonate and zinc chloride mouthwashes on incidence and severity of oral mucositis in patients with cancer under chemotherapy

Design

A randomized clinical trial with a control group, with three parallel groups

Settings and conduct

The present study is a three-group clinical trial that will be performed on 144 cancer patients in Hamedan in 1398. Patients will be randomly divided into three groups (two intervention and one control group). In intervention groups patients will receive sodium bicarbonate solution and zinc chloride solutions and control group will receive placebo. People in each of the three groups will rinse for 2 minutes. The interval between two mouthwashes is set at 15 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with cancer aged 18 to 65 years, cancer stage 1 or 2, Absence of oral ulcers, No sensitivity to zinc chloride and sodium bicarbonate
.Exclusion criteria: unwillingness to continue participating in the study, Absence on at least one day of follow-up.

Intervention groups

Intervention group (A): Patients will receive 5% sodium bicarbonate solution every eight hours twice.
Intervention group (B): Patients will receive 0.5% zinc chloride solution every eight hours twice. Control group (placebo) receive 2 cc placebo (distilled water) every eight hours twice. People in each of the three groups will rinse for 2 minutes. The interval between two mouthwashes is set at 15 minutes.

Main outcome variables

Incidence and severity of oral mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N28**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of sodium bicarbonate and zinc chloride mouth washes on incidence and severity of oral mucositis in patients with cancer under chemotherapy

Public title

Comparison the effect of sodium bicarbonate and zinc chloride mouth washes on incidence and severity of oral mucositis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with cancer aged 18 to 65 years
Cancer stage 1 or 2
Absence of oral ulcers
No sensitivity to zinc chloride and sodium bicarbonate

Exclusion criteria:

Absence on at least one day from the days designated for follow-up
Dissatisfaction with continuing to participate in the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation of samples in three groups, 6 blocks will be used as random block allocation. For this purpose, 20 modes of 6-block are written on pieces of paper and put in envelopes and randomly replaced. Patients will be assigned to the intervention or control groups according to the order of the letters of the blocks removed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.UMSHA.REC.1398.335

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 and severity of oral mucositis

Timepoint

Before and up to twenty days after the intervention

Method of measurement

World Health Organization Mucositis Scale

Secondary outcomes

empty

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

Intervention group(1): patients receive 5% sodium bicarbonate solution every 8 hours, 2 times for 21 days.

Category

N/A

2**Description**

Intervention group(2): patients will receive 0.5% zinc chloride solution every 8 hours, 2 times for 21 days.

Category

N/A

3**Description**

Control group(placebo): patients will receive 2 cc placebo (distilled water) every 8 hours, 2 time for 21 days.

Category

N/A

Recruitment centers1**Recruitment center****Name of recruitment center**

Beheshti hospital

Full name of responsible person

Fatemeh Mohamadi

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Deputy of research and technology

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**

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Mohamadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Mohamadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

rameshkamalan98@gmail.com

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Ramesh Kamalan

Position

Student

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