Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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(destilled 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)

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+98 81 3422 5056

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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 centers

1

Recruitment center
Name of recruitment center
Beheshti hospital
Full name of responsible person
Fatemeh Mohamadi
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Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
Street address
Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan
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s_bashirian@umsha.ac.ir
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
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Person responsible for updating data

rameshkamalan98@gmail.com

Contact

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Full name of responsible person
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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Email

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