

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effect of sodium bicarbonate and zinc chloride mouthwashes on treatment of oral mucositis in patients with cancer under chemotherapy in Hamadan Imam Khomeini clinic, 2019

Protocol summary

Study aim

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

Design

Clinical trial with two intervention groups and one control group with parallel, two-way blind groups, randomized

Settings and conduct

This study will be performed blindly in Imam Khomeini Clinic of Hamedan, the participants as well as the person who will analyze the data will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-65 years with stage 1 and 2 cancer who are undergoing chemotherapy and do not have oral ulcers and are not allergic to sodium bicarbonate and zinc chloride and have normal platelet and white blood cell levels. Inclusion criteria: Absence at least one session in the treatment or follow-up phase and hypersensitivity to zinc chloride and sodium bicarbonate, as well as the patient's disability and excessive weakness

Intervention groups

Patients in all three groups will be included in the study from the first day of chemotherapy for 14 days. All patients participating in research will be trained on routine care (teeth brushing, proper nutrition, non-smoking, and tooth health checkup) The intervention group (A) receives 2 times every 8 hours and each time 10 cc 10% sodium bicarbonate solution. The intervention group (B) receives 2 times every 8 hours and each time 10% sulfate solution. The control group (placebo) receives 2 times every 8 hours and each time 10 cc sterilized water solution. Patients will rinse for 2 minutes in all three groups. The time interval between two series of mouthwashes is set to 15 minutes.

Main outcome variables

treatment of oral mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190703044082N3**

Registration date: **2020-11-26, 1399/09/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-26, 1399/09/06**

Update count: **0**

Registration date

2020-11-26, 1399/09/06

Registrant information

Name

Fateme Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 4567 8904

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

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

Comparison of the effect of sodium bicarbonate and zinc chloride mouthwashes on treatment of oral mucositis in patients with cancer under chemotherapy in Hamadan Imam Khomeini clinic, 2019

Public title

The effect of mouthwash on the treatment of oral mucositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Patients with cancer aged 18-65 years
- Stage I and II of Cancer
- Under chemotherapy
- With no oral ulcer
- To be able to carry out a mouthwash
- Having a normal level of white blood cells and platelets
- Not using another medication to prevent and treat oral mucositis
- Not being in pregnancy and lactation time
- Not receiving chemotherapy and radiotherapy simultaneously
- No other physical and mental disorders
- Insensitivity to zinc chloride and sodium bicarbonate
- Receiving at least one drug from the category of commonly used chemotherapy drugs
- Not receiving chemotherapy drugs which increase mucositis, such as actinomycin and ...

Exclusion criteria:

- Absence in at least one session of determined days for treatment follow-up
- Hypersensitivity to zinc chloride and sodium bicarbonate
- Extensive disability and weakness of the patient

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly assign the participants to the zinc chloride, sodium bicarbonate and control groups, write the names of the three groups on a piece of paper and remove them randomly and the order of sampling of the groups will be determined. For random allocation of samples in three groups, 20 blocks of 6 will be used as random block allocation. Thus, the letter A will be considered for the zinc chloride group, the letter B for the sodium bicarbonate group and the letter C for the control group. On pieces of paper, and we will come across randomly. Sampling will then begin according to the possible order.

Blinding (investigator's opinion)

Double blinded

Blinding description

In which patients will be blind about their allocation in

intervention groups. In addition, the person who will analyze the data will be blind about the allocation of people in the groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Hamedan University of Medical Sciences

Street address

Beginning of Khajeh Rashid Blvd, Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838698

Approval date

2020-10-24, 1399/08/03

Ethics committee reference number

IR.UMSHA.REC.1399.651

Health conditions studied

1

Description of health condition studied

cancer

ICD-10 code

D01

ICD-10 code description

Carcinoma in situ of other and unspecified digestive organs

Primary outcomes

1

Description

Treatment of oral mucositis

Timepoint

1 day before the intervention and 1, 4, 7 and 14 days after the intervention

Method of measurement

Visual Analogue Scale, Oral mucositis index, World Health Organization criteria for grading of oral mucositis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group (A) Receives 10% zinc chloride solution 2 times every 8 hours and 10 cc each time. Patients rinse for 2 minutes. The time interval between the two series of mouthwashes is set to 15 minutes.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group (B) receives 10% sodium bicarbonate solution every 8 hours 2 times. Patients rinse for 2 minutes. The time interval between the two series of mouthwashes is set to 15 minutes.

Category

Treatment - Drugs

3

Description

Control group: The control group (placebo) receives 10 cc of sterile water solution twice every 8 hours. Patients rinse for 2 minutes. The time interval between the two series of mouthwashes is set to 15 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomaii Clinic

Full name of responsible person

Ramesh Kamalan

Street address

Beginning of Ayatollah Kashani Boulevard, Hamadan
University of Medical Sciences and Health Services

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6517838698

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fateme Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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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