

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### Evaluation of the effectiveness of N-Acetyl Cysteine mouthwash in preventing the occurrence of chemotherapy-induced oral mucositis in cancer patients referred to Imam Khomeini Hospital in Sari

#### Protocol summary

##### Study aim

Determining the effectiveness of N-Acetyl cysteine (NAC) mouthwash in preventing mucositis caused by head and neck chemotherapy

##### Design

Two arm parallel group randomised trial with blinded outcome assessment. Phase2 on 68 patients, Randomisation will be done through the following site. [www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)

##### Settings and conduct

Mazandaran Faculty of Pharmacy Laboratory, Oncology Department of Imam Khomeini Hospital Mouthwash in similar containers prepared with special codes by the pharmacy department of the Faculty of Pharmacy and provided to patients, and the examiner and the patient do not know the type of mouthwash. Mouthwashes are given to two groups by a final year dental student, and the examination is done by a person who is a specialist in oral diseases and does not know about the groupings and type of mouthwash.

##### Participants/Inclusion and exclusion criteria

Entry criteria: full alertness, reading and writing literacy, oral mucosa health Exclusion criteria: suffering from respiratory diseases, asthma, diabetes and autoimmune diseases Continuous use of painkillers, narcotics, alcohol, cigarettes, antibiotics and mouthwash solution

##### Intervention groups

The intervention group consisted of 34 patients who used N-acetylcysteine mouthwash in the amount of 15 ml twice a day for 30 seconds, and the control group included 34 patients who used the placebo mouthwash in the amount of 15 ml twice a day. It is 14 days to complete the study.

##### Main outcome variables

Intensity of Mucositis, Sex, Age, Mouthwash

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220712055439N1**

Registration date: **2022-08-03, 1401/05/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-08-03, 1401/05/12**

Update count: **0**

##### Registration date

2022-08-03, 1401/05/12

##### Registrant information

##### Name

Anahita Ghorbani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3326 3409

##### Email address

anahita1802@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-23, 1401/05/01

##### Expected recruitment end date

2022-09-23, 1401/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effectiveness of N-Acetyl Cysteine mouthwash in preventing the occurrence of chemotherapy-induced oral mucositis in cancer patients referred to Imam Khomeini Hospital in Sari

## Public title

Evaluation of N-Acetyl Cysteine mouthwash in preventing the occurrence of chemotherapy-induced oral mucositis

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Cancer patients undergoing chemotherapy for the first time Patients who do not have other systemic diseases

### Exclusion criteria:

Patients who have other systemic diseases Taking antibiotics, drugs, cigarettes and other mouthwashes

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator

## Sample size

Target sample size: 68

## Randomization (investigator's opinion)

Randomized

## Randomization description

The random block method will be used to allocate the samples to two groups. Blocks will be considered as 4 blocks. Therefore, 17 blocks are needed to perform this study. Group type selection for each person will be done through the following site.

[www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Mouthwash is provided to patients in similar containers with specific codes by the Pharmaceuticals Department of the Faculty of Pharmacy, and the examiner, clinical caregivers and the patient do not know the type of mouthwash.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

#### Street address

No. 10, Mahdie 20th Alley, Mahdie St.

#### City

Sari

#### Province

Mazandaran

#### Postal code

4818867479

#### Approval date

2022-06-07, 1401/03/17

#### Ethics committee reference number

1401.181

## Health conditions studied

## 1

### Description of health condition studied

chemotherapy-induced oral mucositis

### ICD-10 code

K12.3

### ICD-10 code description

Oral mucositis (ulcerative)

## Primary outcomes

## 1

### Description

Intensity of Mucositis

### Timepoint

During the 14 days of the study (from the first day to the fourteenth day after the start of chemotherapy)

### Method of measurement

The oral diseases specialist performs the examination based on the classification of the oral mucositis index and records the results in the classification.

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: The intervention group has 34 people and uses N-acetylcysteine mouthwash in the amount of 15 ml twice a day for 30 seconds for 14 days.

### Category

Prevention

## 2

### Description

Control group: The control group also includes 34 patients who use placebo mouthwash in the amount of 15 ml twice a day for 14 days.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Anahita Ghorbani

**Street address**

Razi St.

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Phone**

+98 11 3335 0670

**Fax**

+98 11 3336 3754

**Email**

amir.tasfieh@gmail.com

**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Pedram Ebrahimnezhad

**Street address**

Mazandaran University of Medical Sciences, Valie-Asr Boulevard, Sari, Mazandaran, Iran.

**City**

Sari

**Province**

Mazandaran

**Postal code**

۴۸۱۵۷۳۳۹۷۱

**Phone**

+98 11 3304 4000

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+98 11 3335 2725

**Email**

pebrahimnejad@mazums.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Anahita Ghorbani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Contact**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Anahita Ghorbani

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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**City**

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**Province**

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**Postal code**

4818867479

**Phone**

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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