

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Sep 2026

### Comparison of Anti-inflammatory Effect of Melatonin and Chlorhexidine mouthwashes in People with Gingivitis

#### Protocol summary

##### Study aim

This Clinical Trial Study will be conducted with the aim of Comparing the Anti-inflammatory effect of Melatonin Mouthwash with Chlorhexidine Mouthwash in people with Gingivitis.

##### Design

A Clinical Trial with Control and Intervention groups, Double-blind, is conducted on 56 patients who are divided into two groups of 28 Patients. Using random allocation software 2, patients are distributed into two control and intervention groups (each group includes 28 people) using the randomized block method (blocks of 4).

##### Settings and conduct

In this study, 56 patients referred to the diagnosis department of Sari Dental Faculty, who were diagnosed with Generalized gingivitis (by a specialist in the diagnosis of oral, maxillofacial diseases and a periodontologist), were included in the Enumeration sampling method are studied. The study is Double blind. The patients and the Data collector will not know how the Mouthwash is distributed.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Inclusion Criteria include absence of systemic disease, absence of smoking, absence of pregnancy and absence of gingivitis caused by local Factors such as plaque and Calculus. Exclusion criteria: People who have used antibiotics in the last three months, have a known allergy to compounds containing Melatonin, or have used drugs with a known effect on the periodontium are excluded from the study.

##### Intervention groups

The Control group is the people who are given Melatonin Mouthwash to find out the Anti-inflammatory properties of Melatonin. The Intervention group is the people who are given Gold Standard Chlorhexidine Mouthwash in order to check the Effectiveness of Melatonin.

##### Main outcome variables

Includes GI PI BOP.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230606058391N1**

Registration date: **2023-06-14, 1402/03/24**

Registration timing: **prospective**

Last update: **2023-06-14, 1402/03/24**

Update count: **0**

##### Registration date

2023-06-14, 1402/03/24

##### Registrant information

##### Name

Anahita Ghorbani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3324 4014

##### Email address

nsfma4678@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2023-10-23, 1402/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                                                                                       |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Comparison of Anti-inflammatory Effect of Melatonin and Chlorhexidine mouthwashes in People with Gingivitis                                                                                           |  | City                                                                                                                                                                                                                                                                                                                                                                                                                                                     | sari                   |
| <b>Public title</b>                                                                                                                                                                                   |  | Province                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Mazandaran             |
| Comparing the Effects of Melatonin and Chlorhexidine mouthwash in People with Gingivitis                                                                                                              |  | Postal code                                                                                                                                                                                                                                                                                                                                                                                                                                              | 4816895475             |
| <b>Purpose</b>                                                                                                                                                                                        |  | Approval date                                                                                                                                                                                                                                                                                                                                                                                                                                            | 2023-04-19, 1402/01/30 |
| Prevention                                                                                                                                                                                            |  | Ethics committee reference number                                                                                                                                                                                                                                                                                                                                                                                                                        | IR.MAZUMS.REC.1402.041 |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                   |  | <b>Health conditions studied</b>                                                                                                                                                                                                                                                                                                                                                                                                                         |                        |
| <b>Inclusion criteria:</b>                                                                                                                                                                            |  | <u>1</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                        |
| Systemically Healthy No Smoking Not Pregnant Absence of Gingivitis Caused by Local Factors Such as Plaque and Calculus                                                                                |  | <b>Description of health condition studied</b>                                                                                                                                                                                                                                                                                                                                                                                                           |                        |
| <b>Exclusion criteria:</b>                                                                                                                                                                            |  | Gingivitis                                                                                                                                                                                                                                                                                                                                                                                                                                               |                        |
| People who have used Antibiotics in the last three months Allergy to compounds containing melatonin People who have used drugs with specific effects on periodontium                                  |  | <b>ICD-10 code</b>                                                                                                                                                                                                                                                                                                                                                                                                                                       |                        |
| <b>Age</b>                                                                                                                                                                                            |  | B99.8                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                        |
| No age limit                                                                                                                                                                                          |  | <b>ICD-10 code description</b>                                                                                                                                                                                                                                                                                                                                                                                                                           |                        |
| <b>Gender</b>                                                                                                                                                                                         |  | Other infectious disease                                                                                                                                                                                                                                                                                                                                                                                                                                 |                        |
| Both                                                                                                                                                                                                  |  | <b>Primary outcomes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                  |                        |
| <b>Phase</b>                                                                                                                                                                                          |  | <u>1</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                        |
| 3                                                                                                                                                                                                     |  | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                       |                        |
| <b>Groups that have been masked</b>                                                                                                                                                                   |  | Gingival Index Plaque index Bleeding on probing                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| <ul style="list-style-type: none"> <li>Participant</li> <li>Investigator</li> </ul>                                                                                                                   |  | <b>Timepoint</b>                                                                                                                                                                                                                                                                                                                                                                                                                                         |                        |
| <b>Sample size</b>                                                                                                                                                                                    |  | At the beginning of the study, 7 and 21 days after the start of using the mouthwash                                                                                                                                                                                                                                                                                                                                                                      |                        |
| Target sample size: 56                                                                                                                                                                                |  | <b>Method of measurement</b>                                                                                                                                                                                                                                                                                                                                                                                                                             |                        |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                         |  | Periodontal probe                                                                                                                                                                                                                                                                                                                                                                                                                                        |                        |
| Not randomized                                                                                                                                                                                        |  | <b>Secondary outcomes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                |                        |
| <b>Randomization description</b>                                                                                                                                                                      |  | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                        |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                              |  | <b>Intervention groups</b>                                                                                                                                                                                                                                                                                                                                                                                                                               |                        |
| Double blinded                                                                                                                                                                                        |  | <u>1</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                        |
| <b>Blinding description</b>                                                                                                                                                                           |  | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                       |                        |
| Patients and the person collecting information will not know how mouthwash is distributed, and Mouthwashes will be available to Patients in dark bottles with the Same Color and Shape as Codes 1, 2. |  | Intervention group: The intervention group received 0.2% Melatonin mouthwash. At the same time as mouthwash is given to the patients, they are taught the correct way to brush (Bass) teeth, use dental floss and mouthwash, by the final year student of the project partner. Patients are asked to use 5 ml of mouthwash twice a day for 30 seconds and then not to wash their mouth or eat for an hour. They should do this continuously for 3 weeks. |                        |
| <b>Placebo</b>                                                                                                                                                                                        |  | <b>Category</b>                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| Not used                                                                                                                                                                                              |  | Treatment - Drugs                                                                                                                                                                                                                                                                                                                                                                                                                                        |                        |
| <b>Assignment</b>                                                                                                                                                                                     |  | <u>2</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                        |
| Parallel                                                                                                                                                                                              |  | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                       |                        |
| <b>Other design features</b>                                                                                                                                                                          |  | Control group: The Control group received 0.2% Chlorhexidine mouthwash. At the same time as mouthwash is given to the patients, they are taught the correct way to brush (Bass) teeth, use dental floss and                                                                                                                                                                                                                                              |                        |
| <b>Secondary Ids</b>                                                                                                                                                                                  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| empty                                                                                                                                                                                                 |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| <b>Ethics committees</b>                                                                                                                                                                              |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| <u>1</u>                                                                                                                                                                                              |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| <b>Ethics committee</b>                                                                                                                                                                               |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| <b>Name of ethics committee</b>                                                                                                                                                                       |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| Ethics committee of Mazandaran University of Medical Sciences                                                                                                                                         |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| <b>Street address</b>                                                                                                                                                                                 |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |
| Third floor, Mazandaran University of Medical Sciences, Research and Technology Deputy Buildin, Moalem Square                                                                                         |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                        |

mouthwash, by the final year student of the project partner. Patients are asked to use 5 ml of mouthwash twice a day for 30 seconds and then not to wash their mouth or eat for an hour. They should do this continuously for 3 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tuba clinic, Dr. Beheshti Blvd., Khazar Square

##### Full name of responsible person

Dr.Anahita Ghorbani

##### Street address

Tuba clinic, Dr. Beheshti Blvd., Khazar Square

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816895475

##### Phone

+98 11 3324 4014

##### Email

nsfma4678@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr.Pedram Ebrahimnejad

##### Street address

Mazandaran University of Medical Sciences, Valiasr Blvd., Imam Khomeinei Square

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##### Province

Mazandaran

##### Postal code

4515733971

##### Phone

+98 11 3304 4000

##### Email

pebrahimnejad@mazums.ac.ir

##### Grant name

##### Grant code / Reference number

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

No

##### 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

Dr. Anahita Ghorbani

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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Tuba clinic, Dr. Beheshti Blvd., Khazar Square

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**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