

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
Public title		Province	Mazandaran
Comparing the Effects of Melatonin and Chlorhexidine mouthwash in People with Gingivitis		Postal code	4816895475
Purpose		Approval date	2023-04-19, 1402/01/30
Prevention		Ethics committee reference number	IR.MAZUMS.REC.1402.041
Inclusion/Exclusion criteria		Health conditions studied	
Inclusion criteria:		<u>1</u>	
Systemically Healthy No Smoking Not Pregnant Absence of Gingivitis Caused by Local Factors Such as Plaque and Calculus		Description of health condition studied	
Exclusion criteria:		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		ICD-10 code	
Age		B99.8	
No age limit		ICD-10 code description	
Gender		Other infectious disease	
Both		Primary outcomes	
Phase		<u>1</u>	
3		Description	
Groups that have been masked		Gingival Index Plaque index Bleeding on probing	
- Participant - Investigator		Timepoint	
Sample size		At the beginning of the study, 7 and 21 days after the start of using the mouthwash	
Target sample size: 56		Method of measurement	
Randomization (investigator's opinion)		Periodontal probe	
Not randomized		Secondary outcomes	
Randomization description		empty	
Blinding (investigator's opinion)		Intervention groups	
Double blinded		<u>1</u>	
Blinding description		Description	
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.	
Placebo		Category	
Not used		Treatment - Drugs	
Assignment		<u>2</u>	
Parallel		Description	
Other design features		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	
Secondary Ids			
empty			
Ethics committees			
<u>1</u>			
Ethics committee			
Name of ethics committee			
Ethics committee of Mazandaran University of Medical Sciences			
Street address			
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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahimnejad

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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

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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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