

Application of melatonin (sleep hormone) gel in close proximity to the tooth with gum disease

Submission date 20/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Periodontitis, also known as gum disease, is a serious infection that damages the soft tissues around the teeth. It can lead to tooth loss, difficulty chewing, and other health problems. Despite many treatment options, periodontitis affects 40-90% of the world's population. This study aimed to explore the effectiveness of using melatonin, a hormone with antibacterial and immune-boosting properties, as a local drug delivery (LDD) treatment for periodontitis.

Who can participate?

Adults aged 20 to 45 years diagnosed with periodontitis were recruited for the study.

What does the study involve?

Participants were undergoing periodontal treatment at the Periodontology department. They were randomly assigned to receive either standard treatment (scaling and root planing, SRP) alone or SRP combined with melatonin gel (LDD). Oral cavity examinations were conducted at the start, one month, and three months after treatment. The study lasted four months in total.

What are the possible benefits and risks of participating?

Participants could benefit from reduced progression of periodontal disease both immediately and in the long term. No risks were observed in the participants.

Where is the study run from?

The study was conducted at the Periodontology department, College of Dental Sciences, Davanagere.

When is the study starting and how long is it expected to run for?

November 2019 to September 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Rashmi Srinath, rashmisriperio@yahoo.co.in

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Evaluation of melatonin gel as local drug delivery system for the treatment of periodontitis: a randomised controlled trial

Study objectives

Melatonin gel 1% (w/v) as a local drug delivery system can reduce the progression of periodontitis in adults aged between 20 to 45 years compared to scaling and root planing alone

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/11/2019, College of Dental Sciences (PO Box 327, Pavilion Road, Beside Bapuji Hospital, Davanagere, 577004, India; +91 8192230432; principalcods@gmail.com), ref: CODS /3230 2019-2020

Study design

Single center interventional parallel group clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Management of stage I to stage III periodontitis in adults

Interventions

Patients with chronic periodontitis were randomly assigned to the test and control groups using computer-generated random numbers following the completion of screening assessments. The test group used Melatonin gel 1% (w/v) as a local medication delivery system in addition to scaling and root planing (SRP), while the control group only included scaling and root planing (SRP). Full mouth plaque score and gingival inflammation were recorded at baseline, 1 month and 3 months, using the plaque index, gingival index and gingival bleeding index. PPD and CAL were measured using UNC-15 probe.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Full mouth plaque score is measured using the plaque index at baseline, 1 month, and 3 months
2. Gingival inflammation is measured using the gingival index at baseline, 1 month, and 3 months
3. Gingival bleeding is measured using the gingival bleeding index at baseline, 1 month, and 3 months
4. Probing pocket depth (PPD) is measured using the UNC-15 probe at baseline, 1 month, and 3 months
5. Clinical attachment level (CAL) is measured using the UNC-15 probe at baseline, 1 month, and 3 months

Key secondary outcome(s)

Salivary Superoxide Dismutase (SOD) levels measured using spectrophotometry at baseline, 1 month, and 3 months

Completion date

30/09/2021

Eligibility

Key inclusion criteria

1. Patients with an age group between 20 and 45 years
2. The selected patients should have mild to moderate periodontal pockets (5-7 mm) clinically with radiographic evidence of bone loss, or periodontitis stage II (maximum probing depth ≤ 5

mm and radiographic bone loss of 15% to 33%, coronal third) and periodontitis stage III (probing pocket depth ≥ 6 mm and radiographic bone loss extending to mid-third of root and beyond) according to the 2017 World Workshop classification

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 years

Upper age limit

45 years

Sex

All

Total final enrolment

44

Key exclusion criteria

1. Suffering from systemic diseases such as migraine, insomnia, as well as smokers, alcoholics, pregnant, and lactating individuals
2. Individuals who had taken antibiotics or anti-inflammatory drugs within the past month were excluded from the study

Date of first enrolment

20/10/2020

Date of final enrolment

30/06/2021

Locations**Countries of recruitment**

India

Study participating centre

Department of Periodontology, College of Dental Sciences

PO Box 327, Pavilion Road, Behind Bapuji Hospital

Davanagere

India

577004

Sponsor information

Organisation

College of Dental Science

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/02/2025	18/02/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes