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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

Registration date
22/10/2024

Overall study status
Completed

Last Edited
18/02/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 plaining 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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures

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

Overall study start date
13/11/2019

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 ≥6mm and radiographic bone loss extending to mid-third of root and be-yond) according to the 2017 World Workshop classification

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
44

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
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Sponsor information

Organisation
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Sponsor type
University/education

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Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal

Intention to publish date
01/10/2024

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