

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 2026

### Evaluation of scaling and root planing effects on salivary melatonin level in patients with chronic periodontitis

#### Protocol summary

##### Summary

Periodontitis is a chronic inflammatory infection in which tissue destruction is associated with an imbalance between oxidant \_antioxidant systems. Melatonin is a biomarker that has an antioxidant action. Non-surgical treatment is one periodontal treatment method that affects etiologic factors. The aim of this study is investigated salivary melatonin concentration and its changes following non-surgical treatment in periodontal disease. Inclusion criteria is patient with severe periodontitis, moderate periodontitis, gingivitis and healthy subjects. Patients with systemic disease will be excluded. Study groups include 45 patients with periodontal disease and 15 healthy subjects selected as controls. Intervention include scaling and root planing. Unstimulated saliva was collected before and after scaling and root planing. Decrease inflammation is expected.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013050613239N1**

Registration date: **2013-09-21, 1392/06/30**

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

Last update:

Update count: **0**

##### Registration date

2013-09-21, 1392/06/30

##### Registrant information

###### Name

Fatemeh Mohammadi

###### Name of organization / entity

Ahvaz Jondishapoor University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1559 3207

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Research and Technology Development Department of Medical Sciences, Ahvaz

##### Expected recruitment start date

2013-09-16, 1392/06/25

##### Expected recruitment end date

2014-02-24, 1392/12/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of scaling and root planing effects on salivary melatonin level in patients with chronic periodontitis

##### Public title

Effect of scaling and root planing on salivary melatonin level

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with severe periodontitis; patients with moderate periodontitis; patients with gingivitis; subjects with periodontal healthy. Exclusion criteria: periodontal treatment or antibiotic therapy within the last 3 months; presence of any systemic disease (e.g., diabetes mellitus, asthma); working in night shifts; xerostomia or any other disease of the salivary glands; less than 20 teeth; intake of any drug known to alter melatonin levels (e.g., for sleeping disorders) or to

be immunosuppressive; usage of partial or total prosthesis; pregnancy; lactation; acute infection; immunodeficiency; history of radio- or chemotherapy; and any conditions necessitating antibiotic premedication for dental appointment.

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ahvaz University of Medical Sciences

**Street address**

Mehr street, Golestan

**City**

Ahvaz

**Postal code****Approval date**

2012-11-19, 1391/08/29

**Ethics committee reference number**

eth578

**Health conditions studied****1****Description of health condition studied**

Chronic periodontitis

**ICD-10 code**

K05.3

**ICD-10 code description**

Chronic periodontitis

**Primary outcomes****1****Description**

Melatonin

**Timepoint**

Before intervention

**Method of measurement**

Concentration

**Secondary outcomes****1****Description**

Severity of disease

**Timepoint**

After intervention

**Method of measurement**

Pocket depth

**Intervention groups****1****Description**

Scaling and root planning

**Category**

Treatment - Other

**2****Description**

No intervention

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Mohammadi

**Street address****City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Development Deputy of Avaz University

**Full name of responsible person**

Dr Mostafa Fegghi

**Street address**

Medical science university, Mehr street, Goletan

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Development Deputy of Avaz University

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr Leila Golpasand

**Position**

Attend of Periodontal Surgery Department

**Other areas of specialty/work**

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**Sharing plan**

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

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty