

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Evaluation of placebo effect for pain control during scaling and root planning

#### Protocol summary

##### Summary

One hundred eighty two patients are recruited from those needing scaling and root planing referred to the Guilan University of Medical Sciences, Dental Faculty, Department of Periodontology. Following initial examination and obtaining informed consent, participants are divided into two groups using a randomized block design. Group 1 receives one capsule containing starch as a placebo half an hour before the procedure and they are told that the drug is a potent pain killer, while the other group receives no additional treatment rather than scaling and root planing. For each patient demographic characteristics and periodontal parameters are recorded before treatment and they are asked to complete a modified dental anxiety index questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212041081N6**

Registration date: **2013-03-03, 1391/12/13**

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

Last update:

Update count: **0**

##### Registration date

2013-03-03, 1391/12/13

##### Registrant information

###### Name

Golpar Radafshar

###### Name of organization / entity

Guilan University of Medical Sciences, School of dentistry

###### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1323 0775

##### Email address

golshad@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of Research, Guilan University of Medical Sciences

##### Expected recruitment start date

2012-12-20, 1391/09/30

##### Expected recruitment end date

2013-07-20, 1392/04/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of placebo effect for pain control during scaling and root planning

##### Public title

Pain control induced by placebo effect during scaling and root planing

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Volunteers seeking scaling and root planing and have either gingivitis or periodontitis are selected. Inclusion criteria: Being in a good general health; having at least 3 standing teeth in each sextant of dentition; not consuming any drugs such as anti-depressants; corticosteroids; ant-coagulants; NSAIDs; anti-inflammatory; and etc. Patients needing anti-biotic prophylaxis, as well as pregnant or lactating women are excluded from the study.

##### Age

No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **182**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
Visual analogue Scale and a five -point verbal rating Scale are used for pain measurement. To eliminate effects of anxiety on pain reported by the patients, a Modified Dental anxiety Scale is used. In case of severe and non-tolerable pain during procedure, local anesthesia by infiltration injection is performed as a rescue analgesic medication.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

guilan university of medical sciences

**Street address**

Namjoo BLV, Mellat Str. Guilan University of Medical Sciences Building

**City**

rasht

**Postal code**

4188794755

**Approval date**

2013-02-09, 1391/11/21

**Ethics committee reference number**

3910396405

## Health conditions studied

### 1

**Description of health condition studied**

pain during scaling and root planing

**ICD-10 code**

K05.1

**ICD-10 code description**

Chronic gingivitis

### 2

**Description of health condition studied**

Pain during scaling and root planing

**ICD-10 code**

K05.3

**ICD-10 code description**

Chronic periodontitis

## Primary outcomes

### 1

**Description**

pain severity

**Timepoint**

During intervention

**Method of measurement**

visual analogue scale, Five point verbal rating scale

## Secondary outcomes

### 1

**Description**

Treatment of gingivitis and/or periodontitis

**Timepoint**

At the time of admission, and four weeks after scaling

**Method of measurement**

Probing pocket depth

## Intervention groups

### 1

**Description**

Placebo capsule, one single dose, 0.5 to 1 hour before scaling and root planing

**Category**

Placebo

### 2

**Description**

Control group, no medication before scaling and root planing

**Category**

Treatment - Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Faculty of Dentistry Guilan University of Medical Sciences

**Full name of responsible person**

Golpar Radafshar

**Street address**

No 11, 114th Street, Golsar Blv.

**City**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-chancellor for research, Gillan University of Medical Sciences

**Full name of responsible person**

Mrs.Susan Komaie

**Street address**

Research and Technology Building,Namjoo Street, Gaz Square

**City**

rasht

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for research, Gillan University of Medical Sciences

**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**

Oral and Maxillofacial Developmenatal Disease Research Center

**Full name of responsible person**

Nastaran Mirfarhadi

**Position**

MS Nursing education

**Other areas of specialty/work**
**Street address**

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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**

Guilan University of Medical Sciences, Faculty of Dentistry, Department of Periodontology

**Full name of responsible person**

Golpar Radafshar

**Position**

Head of Oral and Maxillo-facial Developmental Disease Research Center/ Associate Professor of Period

**Other areas of specialty/work**
**Street address**

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## Person responsible for updating data

**Contact**
**Name of organization / entity**

Department of Periodontology, Faculty of Dentistry, Guilan University of Medical Sciences

**Full name of responsible person**

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**Position**

Head of Oral and Maxillo-facial Developmental Disease Research Center/ Associate Professor of Period

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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*