Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

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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

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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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