

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of surgical periodontal therapy on gingival cervicular fluid and salivary concentration of L-Plastin in patients with chronic peridontitis

Protocol summary

Summary

The aim of this study is to assess the changes in the concentrations of the L-Plastin in the gingival cervicular fluid and saliva in the patients with chronic periodontitis after periodontal treatment. The study population consists of 20 patients in the control group and 20 patients in the test group. From individuals who were willing to participate in the study, Written and informed consent will obtained . All participants will evaluate clinically and radiographically. Sampling of gingival cervicular fluid & saliva will done at baseline. The gingival cervicular fluid will collected with the periopaper . In the chronic periodontitis groups, the gingival crevicular fluid samples will collect from the mesiobuccal aspect of the tooth with ≥ 5 mm probing depth. In the healthy group , gingival crevicular fluid samples will collect from the mesiobuccal aspect of the tooth exhibiting probing pocket depth up to 3 mm without BOP. for Saliva collection, the subjects will instructed to avoid eating ,drinking and brushing one hour before sampling & rinse their mouth with tap water, following that they expectorated whole saliva into sterile 50-mL tubes for 5 min. the samples were immediately stored at -80°C until required for laboratory analysis. After sampling oral hygiene instruction will done for the patients. For the periodontitis patients scaling & root planing will done. Clinical evaluation will done in periodontitis group 4 weeks later and clinical parameters will register and Second sampling of gingival cervicular fluid & saliva . 4 weeks after completment surgical treatment in the sextants that need surgery, clinical parameters will register & third sampling will done. analysis will done with enzyme-linked immunosorbent assay (ELISA) .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809282885N1**

Registration date: **2017-06-01, 1396/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-01, 1396/03/11

Registrant information

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Name of organization / entity

Qazvin Dental School

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Recruitment status

Recruitment complete

Funding source

private, Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2017-04-01, 1396/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of surgical periodontal therapy on gingival cervicular fluid and salivary concentration of L-Plastin in

patients with chronic peridontitis

Public title
Effect of surgical periodontal therapy on gingival cervicular fluid and salivary concentration of L-Plastin

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: The control group was the people that They had no history of periodontitis ; had more than 20 teeth; They exhibited no sites with > 3 mm probing pocket depth ;No sites with> 1 mm clinical attachment loss; as well as no radiographic evidence of alveolar bone loss. The chronic periodontitis group had more than 20 teeth; had probing pocket depth $\geq$ 5 mm & clinical attachment loss of $\geq$ 3 mm, which was commensurate with the amount of plaque accumulation with radiographic evidence of alveolar bone in at least two quadrant of four quadrant in which at least two teeth in each quadrant have clinical attachment loss & bone loss. Exclusion criteria:chemotherapy; pregnancy; lactation; HIV; systemic disease like respiratory & cardiovascular disease; getting antibiotic & other drugs within 4 months ago; getting periodontal therapy in the past.

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: **40**

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

Ethics Committee Qazvin Medical Science School

Street address

Bahonar blvd, Qazvin

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Postal code

59811-34197

Approval date

2016-05-25, 1395/03/05

Ethics committee reference number

IR.QUMS.REC.1395.11

Health conditions studied

1

Description of health condition studied

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic pericoronitis Periodontitis: NOS complex simplex

Primary outcomes

1

Description

L plastin concentration

Timepoint

Baseline, one month after oral hygiene instruction & scaling & root planing and one month after completion of flap surgeries

Method of measurement

Analysis done with ELIZA , picogram /ml

Secondary outcomes

1

Description

Probing depth

Timepoint

Baseline, One month after oral hygiene instruction and scaling & root planing and one month after completion of flap surgeries

Method of measurement

Milimeter with periodontal probe

2

Description

Attachment loss

Timepoint

Baseline,One month after oral hygiene instruction and scaling & root planing and one month after completion of flap surgeries

Method of measurement

Milimeter with periodontal probe

3

Description

Plaque index

Timepoint

Baseline, One month after oral hygiene instruction and scaling & root planing and one month after completion of flap surgeries

Method of measurement

Oraly plaque index

4**Description**

Bleeding on probing

Timepoint

Baseline, One month after oral hygiene instruction and scaling & root planing and one month after completion of flap surgeries

Method of measurement

Dichotomous measurement of bleeding on probing

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

In case group after oral hygiene instruction and scaling & root planing after one month flap surgery will done in quadrant that needs surgery.

Category

Treatment - Surgery

2**Description**

In control group no intervention will done

Category

N/A

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

Qazvin Dental School

Full name of responsible person

Dr Shadi Assareh

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

Vice Chancellor for Research, Qazvin University of Medical Sciences

Full name of responsible person

Shahrazad Gholami

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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, Qazvin 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**

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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