Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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 ≥ 5 mm & clinical attachment loss of ≥ 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
City
Qazvin
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
KO5.3
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 plannng 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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Qazvin Medical Science School, bahonar blvd, Qzvin,
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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
Shahrzad Gholami
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Qazvin bahonar blvd
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Qazvin
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
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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