

# 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  $\geq 5$  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

###### Name

Asieh Mozaffari

###### Name of organization / entity

Qazvin Dental School

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Iran (Islamic Republic of)

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asiehmozaffari@yahoo.com

##### 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

##### 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

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 &amp; 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 &amp; 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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**City**

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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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Dr Asieh Mozaffari

**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*