Effect of non-surgical periodontal therapy on serum transferrin levels in chronic periodontitis patients

Protocol summary

Summary
Objectives: The aim of this study is to measure the concentration of transferrin in serum from patients with and without chronic periodontitis before and after non-surgical periodontal therapy and test whether these concentrations correlate with clinical parameters associated with periodontal disease. Design: in this single center, single blind, non-randomized controlled trial, individuals are in 25-60 age that referred to dental school of Tabriz and after receiving the written consent will enter to this study. Forty individuals are included in this study, 20 with chronic periodontitis (at least two interproximal sites with attachment loss equal or more than 4mm) and 20 with periodontally health (no interproximal attachment loss). Setting and conduct: serum transferrin levels (by venus blood sample) and clinical periodontal parameters (PD, CAL, BOP, GI, PI by periodontal probe) are recorded at baseline and 3 months after non-surgical periodontal therapy. Major exclusion criteria: a course of NSAIDs, antimicrobial drugs & periodontal treatment within a 6 month period before the study, presence of any systemic disease and infection other than chronic periodontitis, pregnancy or lactating mothers. Intervention: Patients in the chronic periodontitis group received nonsurgical periodontal therapy, including oral hygiene instructions (flossing & brushing with Bass technique), and scaling and root planing in one 1 hour session. Then, 0.12 % chlorhexidine mouthwash (Cosmedent Co., Gingival KIN, Spain) was prescribed for 14 days (15ml for 30 seconds twice a day). Control group subjects were provided with oral hygiene instructions (flossing & brushing with Bass technique) only in 1 20 minute session. Main outcome variables: serum transferrin is a primary outcome and clinical periodontal parameters are a secondary outcome.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT201601137128N6
Registration date: 2016-04-26, 1395/02/07
Registration timing: retrospective

Last update:
Update count: 0
Registration date
2016-04-26, 1395/02/07
Registrant information
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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research of Tabriz university of medicial csiences

Expected recruitment start date
2015-04-05, 1394/01/16
Expected recruitment end date
2016-04-05, 1395/01/17
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Effect of non-surgical periodontal therapy on serum
transferrin levels in chronic periodontitis patients

Public title
Effect of non-surgical periodontal therapy on serum level of transferrin and clinical parameters in patients with periodontal disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria in periodontally healthy group: no evidence of interproximal attachment loss, no PD equal or more than 3mm at any sites on any teeth and whole-mouth bleeding scores equal or less than 10%. Inclusion criteria in chronic periodontitis group: two or more interproximal sites with attachment loss equal or more than 4mm, or two or more interproximal sites with PD equal or more 5mm, not on same tooth. Exclusion criteria: 1) a course of NSAIDs or antimicrobial drugs within a 6 month period before the study 2) history of any periodontal treatment within a 6 month period before the study 3) presence of any systemic disease and infection other than chronic periodontitis 4) presence of aggressive periodontitis 5) pregnancy or lactating mothers 6) use of mouthwashes or vitamin supplements within the previous 3 months 7) furca involvement grade 2, 3, 4

Age
From 25 years old to 60 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 Tabriz univercity of medical science

Street address
Golgasht street, daneshgah street, Tabriz

City
Tabriz

Postal code

Approval date
2016-01-13, 1394/10/23

Ethics committee reference number
tbzmed.rec.1394.870

Health conditions studied

1

Description of health condition studied
Chronic periodontitis

ICD-10 code
K05.3

ICD-10 code description
Chronic periodontitis

Primary outcomes

1

Description
serum level of transferrin

Timepoint
Base line-3month

Method of measurement
laboratory test

Secondary outcomes

1

Description
Clinical parameters of periodontium

Timepoint
Base line-3month

Method of measurement
periodontal probing

Intervention groups

1

Description
Intervention: chronic periodontitis: Patients in the chronic periodontitis group received nonsurgical periodontal therapy, including oral hygiene instructions (flossing & brushing with Bass technique), and scaling and root planing in one 1hour session.then, 0.12 % chlorhexidine mouthwash (Cosmodent Co., Gingival KIN, spain) was prescribed for 14 days (15ml for 30seconds twice a day).

Category
Treatment - Other

2

Description
Control: healthy periodontal control group subjects were provided with oral hygiene instructions (flossing & brushing with Bass technique) only in 1 20minute session
Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry faculty of tabriz, Periodontics ward
Full name of responsible person
dr Adileh Shirmohamadi
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Golgasht street, Daneshgah street, Tabriz, Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor for research of tabriz university of medical sciences
Full name of responsible person
Nasser asl aminabadi
Street address
Tabriz university of medical science, Golgasht street, D
City
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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 of tabriz 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

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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