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 or antimicrobial drugs and 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 (Cosmodent 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 medical sciences

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
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**

N/A

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

N/A

**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

Golasht 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 1 hour session. then, 0.12% chlorhexidine mouthwash(Cosmodent Co., Gingival KIN, spain) was prescribed for 14 days (15ml for 30 seconds 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 20 minute 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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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

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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

Person responsible for general inquiries

Contact
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Drashkan Salari

Position
Resident of periodontics

Other areas of specialty/work

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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