Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Green tea effects on clinical indexes and Salivary Cytokines level of Patients with chronic periodontitis as first phase complement for periodontal treatment

Protocol summary

Summary

Objectives: Green tea effects on patients with chronic periodontitis as first phase complement for periodontal treatment Design: Systematic effects of green tea due to its antibacterial and anti-inflammatory especially in inaccessible places for scaling as first phase complement of periodontal treatment (sanitarian education and scaling and root planning) Setting and conduct: Patients are selected from department of periodontology in Shahed School of Dentistry based on inclusion criteria and getting individuals written consents. Afterwards, clinical criteria are recorded and saliva samples are taken. In the following, in addition to teeth scaling, green tea is given to the intervention group in order to drink according to given instructions and the control group only takes teeth scaling. Moreover, after six week, clinical criteria are recorded once again and saliva samples are taken. The results of the salvia samples are studied using ELISA test. Dividing the patients into two groups will be done by one person and scaling and saliva samples by someone else. Input conditions: Existence of 2 teeth with 5 millimeters or more teeth pocket depth in each quadrant; existence of bleeding caused by probing (BOP) in pockets with size of 5 millimeters or more; clinical attachments loss which are more than 3 millimeters; research condition acceptance. Output conditions: Catching systemic disease; pregnancy and breastfeeding sicknesses; periodontal treatment receiving in last 6 months; smoking and drinking alcohol; antibiotic and NSAIDs taking history in last 6 months and green tea drinkers who drink more than one cup in a week and a fixed orthodontic appliance people Intervention: Chronic Periodontal patients divide into two groups. In the first group (15 people) the saliva is collected but there will not be any interventions. In this case the group is controlling. In the second group (15 people) patients drink green tea before scaling for 6 weeks. In both groups saliva is collected after 6 weeks Main outcome measures: The amount of 1 and 6 salivary interleukin and clinical criterion (pocket depth, bleeding and plaque indexes).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015113025296N1**
Registration date: **2016-05-21, 1395/03/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name
Gita Rezvani
Name of organization / entity
Shahed University
Country
Iran (Islamic Republic of)
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+98 21 8895 9210
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Recruitment status

Recruitment complete

Funding source

The grant of project executive from vice chancellor for assistance of Shahed University

Expected recruitment start date

2015-02-09, 1393/11/20

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Green tea effects on clinical indexes and Salivary Cytokines level of Patients with chronic periodontitis as first phase complement for periodontal treatment

Public title

Green tea effects on clinical indexes and Salivary Cytokines level of Patients with chronic periodontitis as first phase complement for periodontal treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Existence of 2 teeth with 5 millimeters or more teeth pocket depth in each quadrant; existence of bleeding caused by probing (BOP) in pockets with size of 5 millimeters or more; clinical attachments loss which are more than 3 millimeters; research condition acceptance. Exclusion criteria: Catching systemic disease; pregnancy and breastfeeding sicknesses; periodontal treatment receiving in last 6 months; smoking and drinking alcohol; antibiotic and NSAIDs taking history in last 6 months and green tea drinkers who drink more than one cup in a week; a fixed orthodontic appliance people.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not 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 in research of Shahed University

Street address

Shahed university, front of the Holy Shrine of Imam Khomeini, Persian Gulf Highway (Tehran-Qom), Tehran, Iran

City

Tehran

Postal code

Approval date

2014-12-29, 1393/10/08

Ethics committee reference number

shahed.rec.1393/29

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

Gingival bleeding index (Ainamo & Bay)

Timepoint

6 week

Method of measurement

William`s periodontal probe

2

Description

Plaque index (O'leary index)

Timepoint

6 week

Method of measurement

William`s periodontal probe

Secondary outcomes

1

Description

IL1 beta consentration

Timepoint

6 week

Method of measurement

ELISA

2

Description

IL6 consentration

Timepoint

6 week

Method of measurement

ELISA

Intervention groups

1

Description

1.75 gram green tea in 500 milliliter boiling water as an anti-inflammatory and anti-bacterial agent twice in day for 6 week after first phase of periodontal treatment was prescribed for study group and only first phase of periodontal treatment for control group

Category

Treatment - Other

2

Description

Control group: Only first phase of periodontal treatment will be done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontology department of Shahed university`s dental College

Full name of responsible person

Dr Ferial Taleghani

Street address

Faculty of Dentistry of Shahed University, Italy street, Vesal and Qods interval, Keshavarz Boulevard

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahed university

Full name of responsible person

Dr Zahra Kiasalari

Street address

Shahed university, front of the Holy Shrine of Imam Khomeini, Persian Gulf Highway (Tehran-Qom), Thehran, Iran

City

Tehran

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, Shahed university

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

Dental college of Shahed university

Full name of responsible person

Dr Gita Rezvani, Dr Ferial Taleghani

Position

Assistant professor of oral pathology, Assistant professor of periodontology

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
Maryam Valizadeh, Mahnaz Birjandi

Position
Dentistry student, Dentistry student

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