

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effect of green tea mouthwash on gingival indices in gingivitis suffered patients

#### Protocol summary

##### Summary

Effect of hydroalcoholic extract of green tea mouth wash will be evaluated on gingivitis in this study. The study is double blinded clinical trial. The patients will randomly divide into two groups of test and control. Each group will consist of twenty five patients suffering from plaque induced gingivitis who were referred to periodontics department of Hamadan dentistry faculty. Hydroalcoholic extract of green tea for test group and chlorhexidine mouth wash will be used for control group. Plaque index, bleeding on probing and gingival index variables will measure on base line, one month and two months after mouthwash usage. All examinations and measurements will be done by one dentist with Williams's periodontal probe. Plaque index will be evaluated by disclosing agent.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016111223468N3**

Registration date: **2017-05-03, 1396/02/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-05-03, 1396/02/13

##### Registrant information

###### Name

Nazli Rabienejad

###### Name of organization / entity

Hamadan university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 1059

###### Email address

n.rabinezhad@umsha.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Hamadan University of Medical Sciences

###### Expected recruitment start date

2017-05-10, 1396/02/20

###### Expected recruitment end date

2017-12-10, 1396/09/19

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluation the effect of green tea mouthwash on gingival indices in gingivitis suffered patients

###### Public title

Evaluation the effect of green tea mouthwash on gingival health

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criterion: diagnosis of plaque induced gingivitis.

Exclusion: systemic disease; pregnancy; smoking; antibiotic consumption during study and six month before; any other mouth wash during study.

###### Age

From **20 years** old to **60 years** old

###### Gender

Both

###### Phase

1-2

###### Groups that have been masked

No information

**Sample size**

Target sample size: 50

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamedan University of Medical Sciences

**Street address**

Hamedan University of Medical Sciences, Mardom street

**City**

Hamedan

**Postal code****Approval date**

2016-10-08, 1395/07/17

**Ethics committee reference number**

IR.UMSHA.REC.1395.322

**Health conditions studied****1****Description of health condition studied**

Gingivitis

**ICD-10 code**

K05.1

**ICD-10 code description**

Gingivitis (chronic): NOS desquamative hyperplastic simple marginal ulcerative

**Primary outcomes****1****Description**

Plaque index

**Timepoint**

Baseline, one and two months after

**Method of measurement**

Inspection

**2****Description**

Bleeding on probing

**Timepoint**

Baseline, one and two months after

**Method of measurement**

Periodontal prob

**3****Description**

Gingival index

**Timepoint**

Baseline, one and two months after

**Method of measurement**

Inspection

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: green tea mouth wash twice a day for 2 months

**Category**

Treatment - Other

**2****Description**

Control group: placebo mouthwash twice a day for two months

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hamedan Dental Faculty

**Full name of responsible person**

Nazli Rabinejad

**Street address**

Hamedan Dental Faculty, Mardom street

**City**

Hamedan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeed Bashirian

**Street address**

Hamedan University of Medical Sciences, Mardom street

**City**

Hamedan

**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, Hamedan 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**

Hamedan Dentistry Faculty

**Full name of responsible person**

Nazli Rabinejad

**Position**

Assistant professor

**Other areas of specialty/work****Street address**

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**Web page address****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*