

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the clinical effect of subgingival irrigation with chamomile, Persica and chlorhexidine on periodontal disease

Protocol summary

Study aim

Evaluation of the clinical effect of subgingival irrigation with chamomile on periodontal indices and in comparison with chlorhexidine, persica and normal saline.

Design

A single-blind; non-randomized controlled clinical trial, phase 3 with parallel groups design of 15 patients (4 interventions in each patient); followed for 4 weeks

Settings and conduct

Patients who was referred to periodontology department of Shiraz school of dentistry were included in the study. First session of irrigation was done immediately after the scaling and it was repeated two more times in 48-hour intervals. Patients were recommended not to eat or drink for two hours after the irrigation. The interval between the last teeth brushing and irrigation was considered at least 30 minutes. After 1 month, data were compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate to severe chronic periodontitis, with at least one pocket depth ≥ 5 mm in posterior teeth in each quadrant. Exclusion criteria: sub gingival crown or filling on the desired area, history of allergy to chamomile, need for antibiotic prophylaxis, history of any periodontal treatment and SRP in last 3 months, pregnancy, smokers and patients with medical conditions which interfere with dental treatments.

Intervention groups

Immediately after scaling and root planning, each quadrant was irrigated with chamomile, persica, chlorhexidine 0.2% and normal saline randomly.

Main outcome variables

probing depth, gingival recession, mucogingival junction, bleeding on probing, plaque index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046505N1**
Registration date: **2020-04-09, 1399/01/21**
Registration timing: **retrospective**

Last update: **2020-04-09, 1399/01/21**

Update count: **0**

Registration date

2020-04-09, 1399/01/21

Registrant information

Name

Samira Zahedrozegar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-07-21, 1395/04/31

Actual recruitment start date

2015-12-22, 1394/10/01

Actual recruitment end date

2016-07-21, 1395/04/31

Trial completion date

2016-08-21, 1395/05/31

Scientific title

Evaluation of the clinical effect of subgingival irrigation with chamomile, Persica and chlorhexidine on periodontal disease

Public title

Effect of subgingival irrigation with Chamomile on periodontal disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate to severe chronic periodontitis which has over 3 millimeters attachment loss Having at least 20 teeth Existence of at least a pocket depth of 5 millimeters or more in posterior teeth in each quadrant Slow rate of disease progression without familial aggregation Without any history of systemic disease Volunteers whom was referred to periodontology department of Shiraz school of dentistry

Exclusion criteria:

Any sub gingival crown or filling on the desired area History of allergy to chamomile Need for antibiotic prophylaxis History of any periodontal treatment and SRP in last 3 months Pregnancy Smokers Medical conditions which interfere with dental treatments

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **11**

More than 1 sample in each individual

Number of samples in each individual: **4**

In each quadrant at least one posterior teeth with pocket depth more than 5mm

Actual sample size reached: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants on the research didnt know which irrigation material used,by white labels which hiding names of the vials containing

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz dental school, Ghasrodasht Ave., Shiraz

City

Shiraz

Province

Fars

Postal code

7195615878

Approval date

2015-12-15, 1394/09/24

Ethics committee reference number

IR.SUMS.REC.1394.129

Health conditions studied

1

Description of health condition studied

periodontitis

ICD-10 code

K05.6

ICD-10 code description

Periodontal disease, unspecified

Primary outcomes

1

Description

The rate of periodontal pocket depth

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

periodontal probe

2

Description

the rate of bleeding on probing

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

periodontal probe

3

Description

The rate of dental plaque

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Disclosing agent

4

Description

Gingival recession rate

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

periodontal probe

5

Description

mucogingival junction

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Immediately after scaling, each quadrant went under one of the subgingival irrigation with one of the mentioned materials, randomly. First groups material was Chamomile extract. We placed 40 grams of chamomile flower powder with herbarium code (PM 407) in a paper filter and was Soxhlet extractor (AshkeShishe Co., Iran) solved it in 1 liter of distilled water for 4 hours. 100 cc of it was freeze-dried. At first the percent of dried material was calculated about 8 percent and then the liquid extract was used in the study. These process was repeated every week to make sure that the property was maintained. Irrigation was done by dull insulin syringes which were marked 2mm by a Williams probe. The syringe was placed 2mm under the gingival margin and the volume of the mouth rinse was proportionate to pocket depth as the liquid poured out the pocket. Suction was placed in the mouth in whole time of the irrigation. First irrigation was done immediately after the scaling and it was repeated two more times in 48-hour intervals. Patients were recommended not to eat or drink for two hours after the irrigation. The interval between the last teeth brushing and irrigation was considered at least 30 minutes.

Category

Treatment - Drugs

2

Description

Intervention group: Immediately after scaling, each quadrant went under one of the subgingival irrigation with one of the mentioned materials, randomly. Second group was chlorhexidine 0.2 % (Behsa Pharmaceutical Co., Iran). Irrigation was done by dull insulin syringes which were marked 2mm by a Williams probe. The syringe was placed 2mm under the gingival margin and the volume of the mouth rinse was proportionate to pocket depth as the liquid poured out the pocket. Suction was placed in the mouth in whole time of the irrigation. First irrigation was done immediately after the scaling and it was repeated two more times in 48-hour intervals. Patients were recommended not to eat or drink for two

hours after the irrigation. The interval between the last teeth brushing and irrigation was considered at least 30 minutes.

Category

Treatment - Drugs

3

Description

Intervention group: Immediately after scaling, each quadrant went under one of the subgingival irrigation with one of the mentioned materials, randomly. Third group was persica (Poursina Pharmaceutical Co., Iran). Irrigation was done by dull insulin syringes which were marked 2mm by a Williams probe. The syringe was placed 2mm under the gingival margin and the volume of the mouth rinse was proportionate to pocket depth as the liquid poured out the pocket. Suction was placed in the mouth in whole time of the irrigation. First irrigation was done immediately after the scaling and it was repeated two more times in 48-hour intervals. Patients were recommended not to eat or drink for two hours after the irrigation. The interval between the last teeth brushing and irrigation was considered at least 30 minutes.

Category

Treatment - Drugs

4

Description

Control group: Immediately after scaling, each quadrant went under one of the subgingival irrigation with one of the mentioned materials, randomly. Third group was normal saline. Irrigation was done by dull insulin syringes which were marked 2mm by a Williams probe. The syringe was placed 2mm under the gingival margin and the volume of the mouth rinse was proportionate to pocket depth as the liquid poured out the pocket. Suction was placed in the mouth in whole time of the irrigation. First irrigation was done immediately after the scaling and it was repeated two more times in 48-hour intervals. Patients were recommended not to eat or drink for two hours after the irrigation. The interval between the last teeth brushing and irrigation was considered at least 30 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz dental school

Full name of responsible person

Zahra Emami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Emami
Position
Assistant professor
Latest degree
Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available