Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
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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 Chammomile 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 freez- 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
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Sponsors / Funding sources

1

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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
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Zahra Emami
Position
Assisstant professor
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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