

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Clinical comparison of the effect of Thymus Vulgaris essential oil and Chlorhexidine on Candida albicans accumulated on orthodontic removable plaques

Protocol summary

Study aim

The aims of this study are determining the Effective Concentration of Thymus Vulgaris essential oil on Candidate Albicans and Use of Zataria Multiflora essential oil as an Herbal Disinfectant during the Treatment of Orthodontic as Replacement of Chlorhexidine

Design

Randomized control trial, Two parallel group, double blinded,

Settings and conduct

The study were conducted in private office of one of the researchers in Shiraz. Each group used one of the two solutions, Thymus vulgaris and Chlorhexidine, for one week . After using the following solution, swabs were taken from three points of orthodontic appliance. Patients and researchers who delivering solutions and swabs were blind in this study.

Participants/Inclusion and exclusion criteria

Exclusion criteria: Moderate to Severe Crowding and Irregularity Periodontal Problem Usage of Antimicrobial Mouth Watch Antibiotic therapy within 90 days poor oral hygiene History of rheumatic fever, History of diabetes, hepatic, renal and immune system disease Inclusion criteria: patients aged 7 to 12 with expansion orthodontic appliance.

Intervention groups

At the beginning of the study, the participants with removable orthodontic appliance infected with candida albicans which had been detected by Laboratory sampling, are divided into intervention and control groups. Intervention group obtained a solution containing Thymus Vulgaris and control group containing chlorhexidine. They were asked to spray solutions on to an orthodontic removable appliance. Swab from three specific of removable orthodontic appliance were taken three times: 1. At the beginning of study 2. After two

days 3. After 5 five days

Main outcome variables

The antifungal effect of Thymus Vulgaris on Candida albicans

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041092N1**

Registration date: **2019-11-23, 1398/09/02**

Registration timing: **retrospective**

Last update: **2019-11-23, 1398/09/02**

Update count: **0**

Registration date

2019-11-23, 1398/09/02

Registrant information

Name

Tahereh Baherimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3649 1516

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-20, 1398/01/31

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

2019-04-20, 1398/01/31
Actual recruitment end date
2019-08-22, 1398/05/31
Trial completion date
2019-08-28, 1398/06/06

Scientific title
Clinical comparison of the effect of Thymus Vulgaris essential oil and Chlorhexidine on Candida albicans accumulated on orthodontic removable plaques

Public title
effect of Thymus Vulgaris essential oil on Candida albicans

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with expansion orthodontic appliance
Exclusion criteria:
Moderate to Severe Crowding and Irregularity
Periodontal Problem Usage of Antimicrobial Mouth Watch
Antibiotic therapy within 90 days poor oral hygiene
History of rheumatic fever, History of diabetes, hepatic, renal and immune system disease

Age
From **7 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **30**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and all researchers except that person who determines code to the solutions are blind in this study. Only one researcher who determines color code to the solutions, does not play a role in collecting data is not blind in this study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Azad University of Shiraz

Street address

School of Dentistry, Shiraz Azad University, North ghaani Ave.

City

Shiraz

Province

Fars

Postal code

71993-5

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

IR.IAU.SHIRAZ.REC.1397.004

Health conditions studied

1

Description of health condition studied

In the present study, to find the desired sample size, a number of patients with removable orthodontic plaque in a private clinic were randomly selected. Before starting the study, an interview was conducted with them to evaluate their dental and medical history, oral health status, occlusion and proper dental care and their health status. Of the 43 patients who were sampled, those who had one of the following were excluded from the study, and 36 who were eligible for inclusion in the study were selected for further studies: - No Candida albicans on Orthodontic removable plaque-Large diastema-Periodontal problem-Use Antimicrobial mouthwash-Antibiotic use in the last 3 months-Very poor oral hygiene

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people with Candida albicans on orthodontic removable plaque and Clinical comparison of the effect of Zataria Multiflora essential oil and Chlorhexidine on Candida albicans accumulated on orthodontic removable plaques.

Timepoint

Sampling and Count of Candida albicans colonies at the beginning of the study (before intervention), 2 and 5 days after spraying with 2%Zataria Multiflora essential oil and chlorhexidine.

Method of measurement

Incubator, Autoclave, Optical Microscope - Ultrasonic Bathroom

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in intervention group obtained a solution containing thymus vulgaris 2%. They were asked to spray solutions on to an orthodontic removable appliance. Swab from three specific of removable orthodontic appliance were taken three times: 1. At the beginning of study. 2. After two days. 3. After 5 five days.

Category

Treatment - Drugs

2

Description

Control group: Participants in control group obtained a solution containing Chlorhexidine 0/2%. They were asked to spray solutions on to an orthodontic removable appliance. Swab from three specific of removable orthodontic appliance were taken three times: 1. At the beginning of study. 2. After two days. 3. After 5 five days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Shiraz Azad University

Full name of responsible person

Tahereh Baherimoghadam

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3th Floor , medical Bldg. 11 Alley, Sattarkhan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Tahereh Baheri Moghadam

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Classification of individuals based on the number of Candida albicans grown colonies in three sampling times (Before spraying 2% Thymus Vulgaris essential oil and Chlorhexidine 0.2%, two days and then five days after spraying)

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Every one

Under which criteria data/document could be used

No one is allowed to work on our data

From where data/document is obtainable

send Email to T-baheri@yahoo.com and announce the request.

What processes are involved for a request to access data/document

send Email to T-baheri@yahoo.com and announce the request.

Comments