

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The Comparison of Teriident and Thyme spray in aphthous: a clinical trial

Protocol summary

Study aim

The Comparison of Teriident and Thyme spray in aphthous: a clinical trial

Design

Clinical trials with a control group, randomized. Patients are randomly divided into two groups using SPSS software.

Settings and conduct

This study will be performed on all patients referred to the the School of Dentistry of Islamic Azad University in 2019, whose diagnosis of minor oral aphthous in their oral mucosa has been confirmed. Sampling will be done based on inclusion and exclusion criteria and for each treatment group, 23 samples and a total of 46 samples will be considered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: definitive diagnosis of minor oral aphthous by specialist dentistry, life span is 2 days or less, consent to participate in the study. Exclusion criteria: Pregnancy, concomitant use of any topical drug for the treatment of aphthous, atypical cases of pests and cases suspected of Behcet's syndrome, inflammatory bowel disease, or history of any type of underlying illness that can predispose a person to aphthous, age under 12 years, patients with diseases that impair wound or systemic healing such as diabetes, kidney disease, anemia, liver disease, use of any effective medications for wound healing, such as corticosteroids, anticoagulants, immunosuppressive drugs, chemotherapy, the use of any type of topical or systemic analgesic, and drug and tobacco use

Intervention groups

Control group: In this group, the drug treatment will be with triamcinolone (Triadent oral paste belonging to Raha Pharmaceutical Company) will be applied to the wound 4 times a day for 15 minutes. Intervention group: Thyme spray (Zardband company, Iran) will be sprayed in the mouth 4 times a day after each meal and at bedtime.

Main outcome variables

Clinical parameters include pain intensity and the size of the lesion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049986N1**

Registration date: **2021-01-23, 1399/11/04**

Registration timing: **retrospective**

Last update: **2021-01-23, 1399/11/04**

Update count: **0**

Registration date

2021-01-23, 1399/11/04

Registrant information

Name

Mehrdad Taghibakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2645 0339

Email address

mehrdad.taghibakhsh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-12, 1398/10/22

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

2020-01-12, 1398/10/22

Actual recruitment end date

2020-02-19, 1398/11/30

Trial completion date

2020-02-25, 1398/12/06

Scientific title

The Comparison of Teriadent and Thyme spray in aphthous: a clinical trial

Public title

The Comparison of Teriadent and Thyme spray in aphthous: a clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of minor oral aphthous by specialist dentistry Life span is 2 days or less Consent to participate in the study Age above 12 years

Exclusion criteria:

Pregnancy Concomitant use of any topical drug for the treatment of aphthous. Use of any systemic treatment over the past 3 months. Atypical cases of pests and cases suspected of Behcet's syndrome, Inflammatory bowel disease, or history of any type of underlying illness that can predispose a person to aphthous. Age under 12 years Patients with diseases that impair wound or systemic healing such as diabetes, kidney disease, anemia, liver disease. Use of any effective medications for wound healing, such as corticosteroids, anticoagulants, immunosuppressive drugs, chemotherapy. The use of any type of topical or systemic analgesic. Drug and tobacco use

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **23**

Actual sample size reached: **23**

Randomization (investigator's opinion)

Randomized

Randomization description

نمونه ها به روش در دسترس و غیر احتمالی انتخاب می شوند و از بین آنها بیمارانی که شرایط ورود به مطالعه را داشته باشند انتخاب خواهند شد. سپس بیماران به روش تصادفی ساده (به هر نمونه کدی اختصاص به دو گروه کنترل و SPSS می یابد) و با استفاده از نرم افزار آماری مداخله تقسیم خواهند شد.

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 of Islamic Azad University - Dental Branch Tehran - Iran

Street address

No 9, Zeinali Street, Niavaran Street

City

Tehran

Province

Tehran

Postal code

۱۹۷۸۹۱۷۵۵۴

Approval date

2020-01-11, 1398/10/21

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.060

Health conditions studied

1

Description of health condition studied

Oral Aphthae

ICD-10 code

K12.0

ICD-10 code description

Recurrent Oral Aphthae

Primary outcomes

1

Description

Pain intensity

Timepoint

Before starting treatment and on days 2, 4 and 6 after starting treatment

Method of measurement

with Pain Visual Analogue scale

2

Description

The size of the lesion

Timepoint

Before starting treatment and on days 2, 4 and 6 after starting treatment

Method of measurement

By ruler based on millimeters

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group, the drug treatment will be with triamcinolone (Triadent oral paste belonging to Raha Pharmaceutical Company) will be applied to the wound 4 times a day for 15 minutes.

Category

Treatment - Drugs

2

Description

Intervention group: Thyme spray (Zardband company, Iran) will be sprayed in the mouth 4 times a day after each meal and at bedtime

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Islamic Azad University of Tehran

Full name of responsible person

Mehrdad Taghibakhsh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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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

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

Islamic Azad University

Full name of responsible person

Mehrdad Taghibakhsh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Islamic Azad University

Full name of responsible person

Mehrdad Taghibakhsh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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