

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the effect of a synthetic mouthwash(doxepin, chitosan) on the oral ulcers pain and size in comparison with common analgesic mouthwash (Diphenhydramine, AlMgS, lidocaine gel)

Protocol summary

Study aim

This study is aimed to introduce new composition (chitosan, doxepin) for oral pain relief and size of lesions caused by different etiologies

Design

Patients with oral ulcers will be enrolled in two groups by block randomization. In case group 10 patients will use this formulated mouthwash (chitosan, doxepin) as an analgesic agent. In control group 10 patients will use common prescribed mouthwash (Diphenhydramine 12.5 mg/5ml susp Aluminum Mgs and lidocaine gel 2%) . After gargling these analgesics agent for 5 minute, The VAS of patients will be measured in 5, 15, 30 minute and 1 hour intervals. Both participants in case and control group will use the mouthwash three times a day until they suffer from pain. The VAS will be measured also in day 1,2,3.

This study is second phase of clinical trial.

Settings and conduct

This clinical trial will be done on patients that will be referred to oral and maxillofacial Department of Shiraz Dental School during 2017-2018. A mouthwash will be prescribed for the patients with informed consent . The investigator who evaluate the level of pain and the data analyzer also are blind to the type of prescribed mouthwash.etiologies

Participants/Inclusion and exclusion criteria

Inclusion criteria:The patient who has painful oral lesion (new case of oral lesions without receiving any treatment) who are not pregnant who are not diabetic The patient with no other inflammatory disease Exclusion criteria: The patients who have used any analgesic agents (systemic or local) since 2 days ago The patients who have used anti-inflammatory medication such as corticosteroid since 2 weeks ago

Intervention groups

The participants who will be enrolled in case group (10 patients) will use this formulated mouthwash (chitosan,

doxepin) as an analgesic agent. After gargling these analgesics agent for 5 minute, VAS of patients will be measured in 5, 15, 30 minute and 1 hour intervals. The participants will use this mouthwash three times a day until they suffer from pain.The VAS and size of patients' lesions will be measured after gargling also in day 1,2,3. Any probable side effect of this mouthwash will be evaluated by one week follow up of patients. In control group patients will use common prescribed mouthwash (Diphenhydramine 12.5 mg/5ml susp Aluminum Mgs and lidocaine gel 2%). After gargling these analgesics agent for 5 minute, VAS of patients will be measured in 5, 15, 30 minute and 1 hour intervals. The participants will use their mouthwash three times a day until they suffer from pain and their VAS and size of patients' lesions will be measured after each gargling also in day 1,2,3. Any probable side effect of this mouthwash will be evaluated by one week follow up of patients

Main outcome variables

VAS of patients will be evaluated after gargeling; size of oral ulcers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120101008585N5**

Registration date: **2018-02-01, 1396/11/12**

Registration timing: **prospective**

Last update: **2018-02-01, 1396/11/12**

Update count: **0**

Registration date

2018-02-01, 1396/11/12

Registrant information

Name

Fatemeh Lavaee

Name of organization / entity Shiraz Dental School	block randomization individual Unit of randomization Tools used in randomization is table of random number
Country Iran (Islamic Republic of)	Blinding (investigator's opinion) Single blinded
Phone +98 71 1631 9309	Blinding description The investigator who evaluate the level of pain and the data analyser also are blind to the type of prescribed mouthwash.
Email address lavaeef@sums.ac.ir	Placebo Not used
Recruitment status Recruitment complete	Assignment Parallel
Funding source	Other design features
Expected recruitment start date 2018-02-20, 1396/12/01	Secondary Ids empty
Expected recruitment end date 2018-08-21, 1397/05/30	Ethics committees
Actual recruitment start date empty	1
Actual recruitment end date empty	Ethics committee
Trial completion date empty	Name of ethics committee Ethics committee of Shiraz University of Medical Sciences
Scientific title Evaluation of the effect of a synthetic mouthwash(doxepin, chitosan) on the oral ulcers pain and size in comparison with common analgesic mouthwash (Diphenhydramine, AlMgS, lidocaine gel)	Street address Shiraz University of Medical Sciences, Zand street, Shiraz
Public title Evaluation the effect of a synthetic mouthwash on the oral ulcers pain and size	City Shiraz
Purpose Treatment	Province Fars
Inclusion/Exclusion criteria	Postal code 7195944315
Inclusion criteria: The patient who has painful new oral lesion without receiving any treatment The patients who are not pregnant The patients who are not diabetic The patients with no other inflammatory diseases The patients who sign the written consent form	Approval date 2017-12-10, 1396/09/19
Exclusion criteria: The patients who have used any analgesic agents (systemic or local) since 2 days ago The patients who have used any anti-inflammatory medication such as corticosteroid since 2 weeks ago	Ethics committee reference number IR.SUMS.REC.1396.152
Age From 12 years old	Health conditions studied
Gender Both	1
Phase 2	Description of health condition studied oral ulcer
Groups that have been masked	ICD-10 code K12.39
<ul style="list-style-type: none"> • Outcome assessor • Data analyser 	ICD-10 code description Other oral mucositis (ulcerative)
Sample size Target sample size: 20	Primary outcomes
Randomization (investigator's opinion) Randomized	1
Randomization description	Description level of pain
	Timepoint after gargling these analgesics agent for 5 minute, VAS of patients will be measured in 5, 15, 30 and 1 hour intervals. Their VAS will be measured after each gargling also in day 1,2,3.

Method of measurement

visual analogue scale

2**Description**

The size of oral ulcer

Timepoint

The size of oral lesions will be measured after gargling in day 1,2,3 in intervention and control groups.

Method of measurement

scaled tongue blade

Secondary outcomes**1****Description**

the side effects of using mouth washes

Timepoint

day 1,2,3 and a week after using mouth wash

Method of measurement

asking the patient

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

Intervention group: in main intervention group the patients will use this formulated mouthwash (chitosan, doxepin) made in Shiraz Pharmacy University as an analgesic agent. The participants will use their mouthwash three times a day until they suffer from pain.

Category

Treatment - Drugs

2**Description**

Control group: In control group patients will use common combination ,Diphenhydramine HCL 12.5 mg/5ml(Alhavi) AND suspension Aluminium MgS(Tolid-daru) and lidocaine gel 2%(Sina Daru). The participants will use their mouthwash three times a day until they suffer from pain.

Category

Treatment - Drugs

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

Shiraz Dental Faculty

Full name of responsible person

Fatemeh Lavaee

Street address

Shiraz Dental Faculty, Ghasrdasht street, Shiraz

City

Shiraz

Province

Fars

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0713

Phone

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Email

fatemeh.lavaee@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand street, Shiraz

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Email

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Grant name**Grant code / Reference number**

1396-01-99-14892-115928

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

Fatemeh Lavaee

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

assistant professor

Latest degree**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

specific participant data sets are to be shared (e.g., all collected deidentified IPD, IPD collected for the primary outcome mean and statistical analysis)

When the data will become available and for how long

starting 1year after publication

To whom data/document is available

The researcher who will email the responsible individual in this study and send the request

Under which criteria data/document could be used

The researcher who will email the responsible individual in this study and this person should be an academic member of medical universities.

From where data/document is obtainable

The data will be obtainable by email.

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

The researcher who will email the responsible individual in this study and send the request.

Comments