

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 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

|                                        |                                                                                                                                                                                                                                                 |                                                                                                                                                                                           |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name of organization / entity</b>   | Shiraz Dental School                                                                                                                                                                                                                            | block randomization individual Unit of randomization                                                                                                                                      |
| <b>Country</b>                         | Iran (Islamic Republic of)                                                                                                                                                                                                                      | Tools used in randomization is table of random number                                                                                                                                     |
| <b>Phone</b>                           | +98 71 1631 9309                                                                                                                                                                                                                                | <b>Blinding (investigator's opinion)</b>                                                                                                                                                  |
| <b>Email address</b>                   | lavaeef@sums.ac.ir                                                                                                                                                                                                                              | Single blinded                                                                                                                                                                            |
| <b>Recruitment status</b>              |                                                                                                                                                                                                                                                 | <b>Blinding description</b>                                                                                                                                                               |
| <b>Recruitment complete</b>            |                                                                                                                                                                                                                                                 | The investigator who evaluate the level of pain and the data analyser also are blind to the type of prescribed mouthwash.                                                                 |
| <b>Funding source</b>                  |                                                                                                                                                                                                                                                 | <b>Placebo</b>                                                                                                                                                                            |
|                                        |                                                                                                                                                                                                                                                 | Not used                                                                                                                                                                                  |
|                                        |                                                                                                                                                                                                                                                 | <b>Assignment</b>                                                                                                                                                                         |
|                                        |                                                                                                                                                                                                                                                 | Parallel                                                                                                                                                                                  |
|                                        |                                                                                                                                                                                                                                                 | <b>Other design features</b>                                                                                                                                                              |
|                                        |                                                                                                                                                                                                                                                 |                                                                                                                                                                                           |
| <b>Expected recruitment start date</b> | 2018-02-20, 1396/12/01                                                                                                                                                                                                                          | <b>Secondary Ids</b>                                                                                                                                                                      |
| <b>Expected recruitment end date</b>   | 2018-08-21, 1397/05/30                                                                                                                                                                                                                          | empty                                                                                                                                                                                     |
| <b>Actual recruitment start date</b>   | empty                                                                                                                                                                                                                                           |                                                                                                                                                                                           |
| <b>Actual recruitment end date</b>     | empty                                                                                                                                                                                                                                           | <b>Ethics committees</b>                                                                                                                                                                  |
| <b>Trial completion date</b>           | empty                                                                                                                                                                                                                                           | <b>1</b>                                                                                                                                                                                  |
| <b>Scientific title</b>                | 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)                                                     | <b>Ethics committee</b>                                                                                                                                                                   |
| <b>Public title</b>                    | Evaluation the effect of a synthetic mouthwash on the oral ulcers pain and size                                                                                                                                                                 | <b>Name of ethics committee</b>                                                                                                                                                           |
| <b>Purpose</b>                         | Treatment                                                                                                                                                                                                                                       | Ethics committee of Shiraz University of Medical Sciences                                                                                                                                 |
| <b>Inclusion/Exclusion criteria</b>    |                                                                                                                                                                                                                                                 | <b>Street address</b>                                                                                                                                                                     |
| <b>Inclusion criteria:</b>             | 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 | Shiraz University of Medical Sciences, Zand street, Shiraz                                                                                                                                |
| <b>Exclusion criteria:</b>             | 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                                                       | <b>City</b>                                                                                                                                                                               |
| <b>Age</b>                             | From 12 years old                                                                                                                                                                                                                               | Shiraz                                                                                                                                                                                    |
| <b>Gender</b>                          | Both                                                                                                                                                                                                                                            | <b>Province</b>                                                                                                                                                                           |
|                                        |                                                                                                                                                                                                                                                 | Fars                                                                                                                                                                                      |
|                                        |                                                                                                                                                                                                                                                 | <b>Postal code</b>                                                                                                                                                                        |
|                                        |                                                                                                                                                                                                                                                 | 7195944315                                                                                                                                                                                |
|                                        |                                                                                                                                                                                                                                                 | <b>Approval date</b>                                                                                                                                                                      |
|                                        |                                                                                                                                                                                                                                                 | 2017-12-10, 1396/09/19                                                                                                                                                                    |
|                                        |                                                                                                                                                                                                                                                 | <b>Ethics committee reference number</b>                                                                                                                                                  |
|                                        |                                                                                                                                                                                                                                                 | IR.SUMS.REC.1396.152                                                                                                                                                                      |
|                                        |                                                                                                                                                                                                                                                 |                                                                                                                                                                                           |
|                                        |                                                                                                                                                                                                                                                 | <b>Health conditions studied</b>                                                                                                                                                          |
|                                        |                                                                                                                                                                                                                                                 | <b>1</b>                                                                                                                                                                                  |
|                                        |                                                                                                                                                                                                                                                 | <b>Description of health condition studied</b>                                                                                                                                            |
|                                        |                                                                                                                                                                                                                                                 | oral ulcer                                                                                                                                                                                |
|                                        |                                                                                                                                                                                                                                                 | <b>ICD-10 code</b>                                                                                                                                                                        |
|                                        |                                                                                                                                                                                                                                                 | K12.39                                                                                                                                                                                    |
|                                        |                                                                                                                                                                                                                                                 | <b>ICD-10 code description</b>                                                                                                                                                            |
|                                        |                                                                                                                                                                                                                                                 | Other oral mucositis (ulcerative)                                                                                                                                                         |
|                                        |                                                                                                                                                                                                                                                 |                                                                                                                                                                                           |
|                                        |                                                                                                                                                                                                                                                 | <b>Primary outcomes</b>                                                                                                                                                                   |
|                                        |                                                                                                                                                                                                                                                 | <b>1</b>                                                                                                                                                                                  |
|                                        |                                                                                                                                                                                                                                                 | <b>Description</b>                                                                                                                                                                        |
|                                        |                                                                                                                                                                                                                                                 | level of pain                                                                                                                                                                             |
|                                        |                                                                                                                                                                                                                                                 | <b>Timepoint</b>                                                                                                                                                                          |
|                                        |                                                                                                                                                                                                                                                 | 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

**Postal code**

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**Phone**

+98 71 3626 3193

**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

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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

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

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

assistant professor

**Latest degree**

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**Other areas of specialty/work**

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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**

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**