

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effectiveness of a combined mouthwash of pilocarpine and omega-3 emulsion with placebo on oral symptoms of patients with Sjögren syndrome

Protocol summary

Study aim

Determining the effectiveness of combined pilocarpine mouthwash and omega-3 emulsion in improving the oral symptoms of Sjogren's patients compared to placebo.

Design

Clinical trial with control group and parallel design. In this clinical trial, 44 patients with Sjogren's syndrome with symptoms of dry mouth will be included in the study and will randomly be divided into two groups of 22 people. Forty four identical cards, 22 have the letter A and 22 have the letter B, are placed in an envelope in a jumbled manner, and for each patient, we take out one card randomly.

Settings and conduct

This study will be conducted in the Hajar educational-therapeutic center in Shahrekord on patients with Sjogren's syndrome (primary and secondary) with symptoms of dry mouth who have referred to the educational clinic of Hajar Hospital. This clinical trial study will be double-blind; Considering that the contents of the jars are not known, the researcher and the patient are blind to the intervention and the labeling is done with a random code (not with the contents).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18-75 years old; Documented diagnosis of primary or secondary Sjogren's syndrome. Non-inclusion criteria: heart, lung, kidney or digestive system diseases, diabetes and oral ulcers; pregnancy; breastfeeding; being allergic to pilocarpine

Intervention groups

Intervention group: standard treatment plus pilocarpine drug with a concentration of 1% (Sina Daru Company) along with Omega 3 emulsion with a concentration of 1% (Amin Company) in the form of mouthwash. Placebo group: standard treatment plus placebo

Main outcome variables

Saliva weight; Dry mouth questionnaire (XI) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230419057964N1**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name

Sadaf Baghernejad MonavarGilani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6608 0435

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of a combined mouthwash of pilocarpine and omega-3 emulsion with placebo on oral symptoms of patients with Sjögren syndrome

Public title

The effect of Pilocarpine and omega-3 emulsion combined mouthwash on oral symptoms of Sjogren's syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being at the age of 18-75 years old Documented diagnosis of primary or secondary Sjogren's syndrome with symptoms of dry mouth based on ACR criteria

Exclusion criteria:

Patients who are allergic to pilocarpine. Suffering from heart, lung, kidney or digestive system diseases, diabetes and oral ulcers Pregnancy lactation Being allergic to Pilocarpine

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial, 44 patients with Sjogren's syndrome with symptoms of dry mouth were included in the study and were randomly divided into two groups of 22 people under the name of combined pilocarpine and omega-3 emulsion mouthwash group and placebo group. For this purpose, 44 identical cards, 22 of which have the letter A and 22 of which have the letter B, are placed in an envelope in a jumbled manner and for each patient, we take out one card at random. The letter written on the card will show the patient's treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

This clinical trial study will be double-blind; Considering that the contents of the jars are not clear, the researcher is blind to the intervention. Considering that the patient is not aware of the contents and the labeling is done with a random code (not with the contents), the patient is also blind to the intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sharekord University of Medical Sciences

Street address

Kashani street

City

Sharekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Approval date

2023-02-08, 1401/11/19

Ethics committee reference number

IR.SKUMS.MED.REC.1401.057

Health conditions studied

1

Description of health condition studied

Sjögren

ICD-10 code

M35.0

ICD-10 code description

Sicca syndrome [Sjogren]

Primary outcomes

1

Description

The amount of saliva secretion

Timepoint

Before and 15 days after the intervention

Method of measurement

Saliva weight and dry mouth eleven-item questionnaire (XI)

Secondary outcomes

1

Description

Dry mouth score in related questionnaire

Timepoint

Effectiveness of combined pilocarpine mouthwash and omega-3 emulsion before and 15 days after the intervention

Method of measurement

Questionnaire of the list of eleven items of dry mouth (XI)

Intervention groups

1

Description

Intervention group: Standard treatment plus pilocarpine drug with a concentration of 1% (Sina Daru Company) along with Omega 3 emulsion with a concentration of 1% (Amin Company) will be given to the patients in the form of mouthwash. The medicine is prepared in the laboratory of compound medicines in the pharmaceutical care department of Hajar Hospital, and the products are prepared in 120 cc brown bottles and labeled with random codes so that the contents of the bottles are not known. To prepare local mucosal emulsion (mouthwash) "omega three and pilocarpine", from oil in water omega three emulsion 6.7% containing a mixture of Docosahexanoic Acid (DHA) Eicosapentaenoic Acid (EPA) produced in Amin Pharmaceutical Company, Iran and pilocarpine 2 solution % produced in Sina Daru Pharmaceutical Company is used. Before each dose, the patient shakes the medicine bottle well for 30 seconds, then gargles the volume of 5 ml using a measuring cup for one minute, and then spits it. Mouthwash is delivered to patients in a brown glass bottle with a volume of 225 cc for 15 days consumption in the first visit. The amount of saliva secretion is also evaluated by measuring the weight of a weighed cigarette filter placed in the patient's mouth for 5 minutes in both visits (the first day and the 15th day after taking the medicine) by the project manager.

Category

Treatment - Drugs

2

Description

Control group: standard treatment plus placebo. Half-saline (45% sodium chloride) will be used for the placebo solution. The placebo product is prepared in a 120 cc brown glass with exactly the same shape and packaging as the mouthwash and is labeled with random codes so that the contents of the glass are not clear. Before each dose, the patient shakes the medicine bottle well for 30 seconds, then gargles the volume of 5 ml using a measuring cup for one minute, and then spits it. Placebo is delivered to patients in a brown glass bottle with a volume of 225 cc for 15 days at the first visit. The amount of saliva secretion is also evaluated by measuring the weight of a weighed cigarette filter placed in the patient's mouth for 5 minutes in both visits (the first day and the 15th day after taking the medicine) by the project manager.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Teaching Clinic of Hajar Hospital

Full name of responsible person

Mohammad Musavi

Street address

Kashani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Reisi

Street address

Kashani street

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Sharekord

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Sadaf Baghernejad Monavar Gilani

Position

medical assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammad Mousavi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sadaf Baghernejad Monavar Gilani

Position

Medical Assistant

Latest degree

Medical doctor

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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

To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If possible, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable

In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address baghernejad.sadaf@gmail.com or the contact number 00989122982219

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

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments