

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of Autologous Conditioned Serum on eye condition in patients with Sjogren syndrome

Protocol summary

Study aim

The effect of Autologous Conditioned Serum on eye condition in patients with Sjogren syndrome

Design

Twenty patients were selected with Sjogren syndrome with dry eye in both eyes. After obtaining informed consent, they are classified into two groups with Autologous Conditioned Serum (ACS) treatment and control group by receiving artificial tears drop. Patients were randomly assigned to receive 10 cc of blood from a cubital vein injection and collected in an ACS syringe and used to produce ACS. For this purpose, blood in the syringe is incubated for 24 hours at 37 ° C to release growth and anti-inflammatory factors, The blood is then centrifuged at 3000 g for 10 minutes to remove the ACS. After separation, the ACS is filtered with a 0.22 µm filter and stored at -80 ° C until use.

Settings and conduct

Patients are referred to Nikukari Eye Hospital in Tabriz and the following items for the patients who are most relevant, recorded: Tear film breakup time (tBUT), Best corrected visual acuity (BCVA), Fluorescein staining, Rose Bengal staining, Tear film meniscus. After preparation of Autologous Conditioned Serum (ACS) and its quality control, it is delivered to patients for use as ordered by a physician. A second injection is repeated at intervals of 21 days. Then, in order to evaluate the effect of ACS on patients 3 months after the first use, the cases mentioned above will be recorded.

Participants/Inclusion and exclusion criteria

People between the ages of 25-40 years Having Sjogren's Syndrome The availability of individual during the study period

Intervention groups

ACS treatment group; control group recipients of artificial tears drop

Main outcome variables

Tear film breakup time (tBUT), Best corrected visual acuity (BCVA), Fluorescein staining, Rose Bengal

staining, Tear film meniscus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160422027520N16**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-08, 1398/11/19**

Update count: **0**

Registration date

2020-02-08, 1398/11/19

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

Department of Immunology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

Country

Iran (Islamic Republic of)

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+98 41 3336 4665

Email address

yousefime@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Autologous Conditioned Serum on eye condition in patients with Sjogren syndrome

Public title
Treatment of eye problems in Sjogren syndrome with Autologous Conditioned Serum

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People between the ages of 25-40 years Having Sjogren's Syndrome The availability of individual during the study period
Exclusion criteria:
Having a financial incentive to participate in the study or Participate in another study simultaneously Having eye problems for reasons other than Sjogren's syndrome People with malignancy People with diabetes

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
One patient's eye is considered as a control and one eye for intervention

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

تبریز- خیابان دانشگاه- دانشگاه علوم پزشکی تبریز

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-12-23, 1398/10/02

Ethics committee reference number

IR.TBZMED.REC.1398.1000

Health conditions studied

1

Description of health condition studied

Dry eye in Sjogren syndrome

ICD-10 code

M35.0

ICD-10 code description

Sicca syndrome [Sjogren]

Primary outcomes

1

Description

The effect of Autologous Conditioned Serum on eye condition in patients with Sjogren syndrome

Timepoint

3 months after using autologous conditioned serum injection

Method of measurement

With tests: Tear film breakup time (tBUT), Best corrected visual acuity (BCVA), Fluorescein staining, Rose Bengal staining, Tear film meniscus

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients receiving Autologous Conditioned Serum (ACS) as the intervention group. blood was taken by ACS-specific syringe, manufactured by Orthokin Co., for ACS preparation. Then patients are given ACS to pour 6 drops in one eye daily for 3 months.

Category

Treatment - Other

2

Description

Control group: patients receiving artificial tears drop as the control group. Patients are given artificial tears drop to pour 6 drops in one eye daily for 3 months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikukari Eye Hospital

Full name of responsible person

Mehdi Yousefi

Street address

Nikukari Eye Hospital,Abbasi St,Tabriz, East
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmoodpoor

Street address

Tabriz University of Medical Sciences, Golgasht
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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Yousefi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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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