

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Therapeutic effect of 0.5% thymolol eye drops on rosacea lesions of the face in comparison with placebo

Protocol summary

Study aim

Therapeutic effect of 0.5% timolol eye drops on facial rosacea lesions in comparison with placebo in patients referred to the dermatology clinic of Razi Hospital and Imam Khomeini Hospital in Tehran in 2022 and 2023

Design

Clinical trial with control group, parallel groups, triple blind, randomized by block randomization, phase 2 clinical study, 2 groups of 22 people

Settings and conduct

The study includes 2 groups of 22 people. After referring to the skin diseases and leprosy research center and taking the necessary measurements, according to the randomization table, the patients will receive one of the drugs of group a or b. Patients, researchers and analysts do not know which drug group and which placebo group they are receiving. At the beginning of the study, 2 months after receiving the drug and one month after stopping the drug, the measurement of skin erythema and melanin, flushing, skin transparency and patient satisfaction will be checked and recorded using a questionnaire and Vizioface and Mexameter MX18 devices.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have the criteria for the diagnosis of rosacea Ability to visit at the appointed time and cooperate in taking medicine. Not taking other drugs during the study. Exclusion criteria: History of heart problems and asthma. Taking oral or topical medications such as antibiotics within 3 weeks before the study. Pregnancy and breastfeeding

Intervention groups

we have 2 groups of 22 people. 1 group is given a placebo and 1 group is given drops of thymolol. Every night, 2 drops are used on each side of the face. Patients are evaluated at the beginning of the visit and then 2 months after treatment and 1 month after stopping treatment.

Main outcome variables

erythema- flushing- side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220110053685N1**

Registration date: **2022-12-26, 1401/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-26, 1401/10/05**

Update count: **0**

Registration date

2022-12-26, 1401/10/05

Registrant information

Name

ali moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

dralimoradi20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Therapeutic effect of 0.5% thymolol eye drops on rosacea lesions of the face in comparison with placebo

Public title
The effect of timolol eye drops on rosacea

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Ability to cooperate to refer at the appointed time. Ability to cooperate to necessary cooperation in taking the drug. consciously understanding the consent and accepting its provisions. agreeing not to breastfeed and pregnancy during the study and one month later in women of childbearing age. willingness not to take other drugs during the study. Have the criteria for diagnosing rosacea.
Exclusion criteria:
Receive any research medication within 30 days prior to enrollment. history of allergy to beta-blocker, pregnancy or attempt to conceive or breastfeed. severe depression. history of hypotension or bradycardia, history of myocardial infarction or heart failure. history of arrhythmia, history of asthma or bronchospasm. Taking any rosacea stimulant such as calcium channel blocker during the study. taking alpha or beta blocker drugs. not cooperating in the correct use of the drug or visiting at the appointed time. specific exclusion criteria including taking oral or topical drugs such as antibiotics during 3 weeks before Study criteria for excluding diagnostic biopsy including lidocaine allergy or a history of hypertrophic or colloidal scarring.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly assign the samples to two experimental groups, the random block method (block randomization) has been used, considering blocks of 4, 6, and 8. An online software at <https://www.sealedenvelope.com/simple-randomiser/v1/li> sts was used to generate a sequence of random numbers. In order to reproduce the randomization sequence, seed equal to 36821706636683 was used.

Blinding (investigator's opinion)

Triple blinded

Blinding description
The container containing the drug and placebo will be unlabeled, and all the containers will be similar and indistinguishable, and another person will give the desired drug to the patients based on the block order. The doctor, the patient, the person assessing the outcome and the person analyzing will not know the content of the drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research of Imam Khomeini Hospital Complex - Tehran University of Medical Scienc
Street address
taleqani street
City
tehran
Province
Tehran
Postal code
1416613675

Approval date
2021-12-01, 1400/09/10

Ethics committee reference number
IR.TUMS.IKHC.REC.1400.356

Health conditions studied

1

Description of health condition studied
rosacea

ICD-10 code
L71

ICD-10 code description
Rosacea

2

Description of health condition studied
rosacea

ICD-10 code
T44.7X5

ICD-10 code description
Adverse effect of beta-adrenoreceptor antagonists

Primary outcomes

1

Description

Investigation of flushing based on Global Flushing Severity Score criteria.

Timepoint

At the beginning of the study, one month later and two months after the start of the treatment, one month after stopping the medication

Method of measurement

It is scored by the patient based on the Global Flushing Severity Score between 0-10

2

Description

Evaluation of erythema based on the Clinician Erythema Assessment Scale

Timepoint

At the beginning of the study, one month later and two months after the start of the treatment, one month after stopping the medication

Method of measurement

A number between 0 and 4 is given by the doctor based on the Clinician Erythema Assessment Scale

3

Description

evaluation of erythema based on Patient's self assessment criteria

Timepoint

At the beginning of the study, one month later and two months after the start of the treatment, one month after stopping the medication

Method of measurement

It is scored by the patient based on the Patient's self assessment criteria between 0-4

4

Description

evaluation of erythema based on the mx18 probe of the mexameter device

Timepoint

At the beginning of the study, one month later and two months after the start of the treatment, one month after stopping the medication

Method of measurement

mx18 probe of the mexameter device

Secondary outcomes

1

Description

Investigation of the side effects of 0.5% timolol maleate eye drops

Timepoint

At the beginning of the study, one month and two

months after starting the treatment and one month after stopping the medication

Method of measurement

questionnaire

2

Description

Erythema relapse investigation after discontinuation of treatment based on the Clinician Erythema Assessment Scale

Timepoint

A month later, stop taking the medicine

Method of measurement

Doctor evaluation based on Clinician Erythema Assessment Scale between 0-4

Intervention groups

1

Description

Intervention group: Patients in the intervention group are given half percent timolol maleate eye drops from Sina Daru, and two drops of the solution are used on each side of the face once every night before going to bed. Then, patients will be evaluated for erythema, flushing, and side effects at the beginning of treatment and before treatment, one and two months later, and one month after stopping treatment.

Category

Treatment - Drugs

2

Description

Control group: patients are given a medicinal bottle containing distilled water and two drops of the solution are used on each side of the face once every night before going to bed. Then, patients will be evaluated for erythema, flushing, and side effects at the beginning of treatment and before treatment, one and two months later, and one month after stopping treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Safoura Shakoinezhad

Street address

Vahdat Eslami street, after Vahdat Eslami Square, Razi desd end, Tehran, Iran.

City

Tehran

Province

Tehran

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1199663911
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Email
dr.shakoei@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
akbar fotoohi
Street address
16 azar st, pour sina st, tehrqn univercity of medical sciences
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8889 6696
Email
okazi@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
ali moradi
Position
physician
Latest degree
Medical doctor
Other areas of specialty/work
Others
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Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
ali moradi
Position
physician
Latest degree
Medical doctor
Other areas of specialty/work
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Phone
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Email

dralimoradi20@gmail.com

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

all information o patients can be shared without mentioning the name

When the data will become available and for how long

From 6 months after the end of the study until forever.

To whom data/document is available

Researchers and pharmaceutical companies

Under which criteria data/document could be used

For scientific studies and use in therapy

From where data/document is obtainable

tehran univercity of medical sciences

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

By sending an email to Tehran University of Medical Sciences and after reviewing the action is done.

Admin@irct.ir

Comments