

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation of the effect of IPL with and without intradermal injection of tranexamic acid in treatment of resistant post acne Erythema , An split face control trial in loghman hakim hospital in 1401

Protocol summary

Study aim

To evaluate the effect of IPL laser with and without intradermal injection of tranexamic acid in post acne erythema.

Design

In this phase 3 clinical trial, a study is conducted on 25 patients with stable post-acne erythema. On one side of the face, the intervention is performed, and the other side of the face is considered as the control group, and to choose the intervention side, the randomization method is used by tossing a coin. It is possible to check the treatment response and compare the two sides of the face by a dermatologist who is unaware of the assignment of the facial area to receive tranexamic acid or placebo in a double-blind manner.

Settings and conduct

In this study, among the patients referred to Logman Hakim Hospital, qualified individuals are selected by the researcher and referred to Bahar Clinic for intervention, where the intervention is performed by the researcher on one side of the face that the patient is unaware of.

Participants/Inclusion and exclusion criteria

People with persistent post acne erythema at least for 3 months in the age range of 16 to 40 years , without coagulation disorders ,cancers, sensitivity to drugs, drug interactions , pregnancy,breastfeeding,oral and topical use of retinoids ,tendency to create keloids , photo sensitivity ,use of topical exfoliating drugs.

Intervention groups

we have performed IPL laser on both sides of the face , and on one side of the face, we have intra dermal injection of tranexamic acid , and on the other side, we have injection of normal saline as control group.

Main outcome variables

Examining the degree of improvement of acne induced - erythema by the dermatologist, the degree of patient satisfaction with the improvement of erythema on each

side of the face, examination of side effects after laser and injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221206056736N1**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Nushin Golchin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4469 7518

Email address

nushin.golchin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of the effect of IPL with and without intradermal injection of tranexamic acid in treatment of resistant post acne Erythema , An split face control trial in loghman hakim hospital in 1401

Public title
effect of IPL with and without intradermal injection of tranexamic acid in treatment of post acne Erythema

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
people with persistent post acne erythema that did not improve for at least 3 months in the age range of 16 to 40 years
Exclusion criteria:
coagulation disorders such as DIC ,pulmonary embolism,stroke,DVT suffering from cancers sensitivity to tranexamic acid in previous use consumption of drugs that interfere with the use of tranexamic acid (anticoagulants,estrogenic drugs,tretinoin and anti inhibitory coagulation concentrates)
pregnancy,breastfeeding and the decision to become pregnant oral and topical use of retinoids in the last 6 months prone to keloid formation photosensitivity the use of exfoliating topical drugs including AHA

Age
From **16 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **25**
More than 1 sample in each individual
Number of samples in each individual: **2**
Intervention is done on one side of the face and the other side of the face is used as a control group

Randomization (investigator's opinion)
Randomized

Randomization description
Flip the coin, when the coin comes to the heads side , the right side of the face is intervened, and when the coin comes to the tails,the left side of the face is intervened.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient is unaware of the side of the intervention and examination of treatment response and comparison of two sides of the face by a dermatologist who is unaware of the assignment of the facial area to receive

tranexamic acid or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid beheshti University of Medical Sciences
Street address
Shahid beheshti univerciyt,arabi Ave
City
Tehran
Province
Tehran
Postal code
1985717443

Approval date
2022-11-09, 1401/08/18

Ethics committee reference number
IR.SBMU.SRC.REC.1401.012

Health conditions studied

1

Description of health condition studied
post acne erythema

ICD-10 code
L70.0

ICD-10 code description
Acne vulgaris

Primary outcomes

1

Description
Erythema improvement on the right and left side of the face

Timepoint
The beginning of the study, day 21, day 42, day 72

Method of measurement
Scale of Clinician erythema assessment

2

Description
Patient satisfaction from treatment on the right and left side compared to before

Timepoint
The beginning of the study, day 21, day 42, day 72

Method of measurement

Asking the patient to choose a number from 1 (low) to 4 (very high) ,from the level of satisfaction with the treatment on each side of face

Secondary outcomes

1

Description

The side effects

Timepoint

The beginning of the study, day 21, day 42, day 72

Method of measurement

Questions and comparisons

Intervention groups

1

Description

Intervention group: On the selected side of the face, ampoules of 500mg/5ml tranexamic acid will be injected intradermally by 1cc syringes at a distance of one centimeter in the areas with erythema caused by acne inflammation in the same session.

Category

Treatment - Drugs

2

Description

Control group: On the other side of the face, normal saline is injected intradermally by 1cc syringes at a distance of one centimeter in areas with erythema caused by acne inflammation in the same session.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Nushin Golchin

Street address

Makhsos Ave,Loghman Hakim hospital

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5102 5000

Fax

+98 21 5541 7547

Email

Loghman.hospital@sbmu.ac.ir

Web page address

[Https://lhmc.sbmu.ac.ir](https://lhmc.sbmu.ac.ir)

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Shahid Beheshti university,Arabi Ave,Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9780

Email

Info@sbmu.ac.ir

Web page address

[Https://research.sbmu.ac.ir](https://research.sbmu.ac.ir)

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nushin Golchin

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 2,West fahad Allay,Falsafi Ave, Ekbatan town

City

Tehran

Province
Tehran
Postal code
1393843673
Phone
+98 21 4469 7518
Email
Nushin.golchin@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nushin Golchin
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
No 2, West fahad Allay, Falsafi Ave, Ekbatan town
City
Tehran
Province
Tehran
Postal code
1393843673
Phone
+98 21 4469 7518
Email
Nushin.golchin@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nushin Golchin
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work

Dermatology
Street address
No 2, west Farhad Allay, Falsafi Ave, Ekbatan town
City
Tehran
Province
Tehran
Postal code
1393843673
Phone
+98 21 4469 7518
Email
Nushin.golchin@yahoo.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

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

All data is shared after de-identifying people's faces and characteristics. Community Verified icon

When the data will become available and for how long

Since the publication of the results for one year

To whom data/document is available

Researchers

Under which criteria data/document could be used

In order to evaluate the obtained results, unidentifiable photos of the patients can be accessed.

From where data/document is obtainable

Go to Nushin Golchin's email address at Nushin.golchin@yahoo.com.

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

Submit the application and submit valid documents, then check the applicant's profile and send the application file if eligible. Community Verified icon

Comments