

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison efficacy of IPL (Intense pulsed light) combined with oral azithromycin with oral azithromycin alone in the treatment of moderate to severe papulopustular Acne vulgaris.

#### Protocol summary

##### Summary

The aim of this study is to compare the effects of oral azithromycin with IPL with oral azithromycin alone in treating moderate to severe papulopustular acne vulgaris. This study is a randomized, single-center study without placebo-controlled groups. Patients with moderate to severe acne, ranging between 18 to 40 years of age will be enrolled in the study. Patients with a history of connective tissue disease, pregnancy and lactation will be excluded. Forty patients with acne vulgaris referred to Sina hospital, randomly (interlaced) will be divided into two parallel groups of intervention and control. Informed consents will be filled out by participating patients. The intervention group will be treated with azithromycin 250 mg orally per day and IPL once a week, for 5 weeks. The control group will receive only azithromycin 250 mg orally per day. The number of papules and Pustules will be recorded at the beginning and at the end of the study. The primary outcome measure will be reduced number of lesions.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201701099844N4**

Registration date: **2017-06-20, 1396/03/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-20, 1396/03/30

##### Registrant information

###### Name

Mehdi Amirnia

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1540 6612

##### Email address

amirnia@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison efficacy of IPL (Intense pulsed light) combined with oral azithromycin with oral azithromycin alone in the treatment of moderate to severe papulopustular Acne vulgaris.

##### Public title

The effect of laser in the treatment of acne

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with moderate to severe acne; Age ranges between 18 to 40 years. Exclusion criteria: A history of connective tissue disease; Pregnancy and

lactation (breast-feeding); a previous history of keloids and hypertrophic scars; Photosensitivity; History of Isotretinoin consumption during the past 6 months.

#### Age

From **18 years** old to **40 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not 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

Third floor, Central Building 2 , Tabriz Medical Sciences University, Gholgasht ave , Tabriz

##### City

Tabriz

##### Postal code

5163639888

#### Approval date

2016-11-07, 1395/08/17

#### Ethics committee reference number

IR.TBZMED.REC.1395.938

## Health conditions studied

### 1

#### Description of health condition studied

Acne vulgaris

#### ICD-10 code

L70.0

#### ICD-10 code description

Acne vulgaris

## Primary outcomes

### 1

#### Description

Severity of acne

#### Timepoint

week zero and third month

#### Method of measurement

Counting

## Secondary outcomes

### 1

#### Description

Number of papule and Pustule

#### Timepoint

week zero and third month

#### Method of measurement

Counting

## Intervention groups

### 1

#### Description

They will Treat with azithromycin 250 mg orally per day and IPL. IPL will perform weekly for 5 weeks for patients in the intervention group. Treatment period is 3 months.

#### Category

Treatment - Other

### 2

#### Description

Control group: Only receive azithromycin 250 mg orally per day. Treatment period is 3 months.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic of Tabriz Sina Hospital

##### Full name of responsible person

Niloofar Afshari

##### Street address

between Montazeri Intersection and Hafez St,Azadi Ave

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Hassan Soleimanpour

**Street address**

Vice chancellor for research, Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, , Daneshgah Avenue, Tabriz, East Azarbayjan, Iran

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

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

Tabriz Medical University

**Full name of responsible person**

Mehdi Amirnia

**Position**

Dermatologist

**Other areas of specialty/work****Street address**

Faculty of medicine, Tabriz University of Medical Sciences, Golgasht st.

**City**

Tabriz

**Postal code**

5163639888

**Phone**

+98 41 3540 6612

**Fax**

+98 41 3540 6612

**Email**

amirniyam@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Amirnia

**Position**

Dermatologist

**Other areas of specialty/work****Street address**

Faculty of medicine, Tabriz University of Medical Sciences, Golgasht st.

**City**

Tabriz

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**Phone**

+98 41 3540 6612

**Fax**

+98 41 3540 6612

**Email**

amirniyam@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Niloofar Afshari

**Position**

Resident of Dermatology

**Other areas of specialty/work****Street address**

Faculty of medicine, Tabriz University of Medical Sciences, Golgasht st.

**City**

Tabriz

**Postal code**

5163639888

**Phone****Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*