

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the therapeutic efficacy of oral azithromycin plus Narrow Band Ultraviolet B (NBUVB) with oral azithromycin alone in the treatment of moderate to severe inflammatory facial acne vulgaris

#### Protocol summary

##### Summary

To compare therapeutic efficacy of oral azithromycin plus Narrow Band Ultraviolet B (NBUVB) with oral azithromycin alone in the treatment of moderate to severe inflammatory facial acne vulgaris. Inclusion criteria: 15-35 Years old patient with moderate to severe inflammatory vulgaris. Exclusion criteria: 1-Pregnancy and breastfeeding; 2-History of topical and systemic anti acne treatment from 1 month ago; 3-Photosensitivity. 94 cases were randomly assigned to two groups: group 1, systemic azithromycin 500 mg every other day and group 2, systemic azithromycin 500 mg every other day plus NBUVB 1200 mj/sec two times weekly for one month. We compared the improvement rate of inflammatory acne lesions totally and differentially between two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112288550N1**

Registration date: **2012-02-04, 1390/11/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-02-04, 1390/11/15

##### Registrant information

##### Name

Esmail Rafiee

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1222 0699

##### Email address

rafiee.e@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2010-03-20, 1388/12/29

##### Expected recruitment end date

2011-11-24, 1390/09/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the therapeutic efficacy of oral azithromycin plus Narrow Band Ultraviolet B (NBUVB) with oral azithromycin alone in the treatment of moderate to severe inflammatory facial acne vulgaris

##### Public title

Narrow Band Ultraviolet (NBUVB) effect on the treatment of inflammatory acne

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Male and female patient with moderate to severe inflammatory vulgaris. Exclusion criteria: 1- Pregnancy and breastfeeding; 2-History of topical and systemic anti acne treatment from 1 month ago; 3- Photosensitivity.

##### Age

From **15 years** old to **35 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **94**

**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**

Ahvaz Jundishapur University of Medical Sciences

**Street address**

Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Postal code**

61335-4156

**Approval date**

2011-02-21, 1389/12/02

**Ethics committee reference number**

ETH054

**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**

inflammatory acne lesions (totally and differentially)

**Timepoint**

1 month

**Method of measurement**

lesion count

**Secondary outcomes****1****Description**

patient's satisfaction of treatment

**Timepoint**

1 month

**Method of measurement**

Patient idea

**Intervention groups****1****Description**

Group 2: systemic azithromycin 500 mg every other day and NBUVB 1200 mj/sec two timesd weekly for one month.

**Category**

Treatment - Devices

**2****Description**

Group 1: systemic azithromycin 500 mg every other day.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emam khomeiny hospital

**Full name of responsible person**

Dr Esmaeil Rafiee, resident of dermatology

**Street address**

Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr Mostafa Fegghi

**Street address**

Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Grant name****Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr Esmail Rafiee

**Position**

Resident of dermatology

**Other areas of specialty/work**

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**Full name of responsible person**

Dr Esmail Rafiee

**Position**

Resident of dermatology

**Other areas of specialty/work**

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**Web page address**

**Person responsible for updating data**

**Contact**

**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*