

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the efficacy of topical azithromycin with oral doxycycline in the treatment of meibomian gland dysfunction: A randomized clinical practice trial

#### Protocol summary

##### Study aim

To assess the efficacy of topical azithromycin drops versus oral doxycycline therapy in meibomian gland dysfunction (MGD).

##### Design

Prospective, randomized, interventional, parallel group design with 60 patients, non-blinded to therapy, single center, clinical trial

##### Settings and conduct

The study patients were recruited from an EYE OPD between December 2019 to June 2020, at Qazi Hussain Ahmad Medical Complex, Nowshera. The groups were divided into two i.e. Topical Azithromycin 1% and Oral Doxycycline 100mg, groups were not blinded to therapy so as the examiners.

##### Participants/Inclusion and exclusion criteria

**Inclusion criteria** All the patients within the specified age group with posterior blepharitis secondary to meibomian gland dysfunction Patients with meibomian gland dysfunction, non responsive to conventional therapy such as lid massage, warm compresses and lid scrubbing  
**Exclusion criteria** En Patients with blepharitis other than posterior one Patients with other inflammatory lid conditions like atopic blepharoconjunctivitis Patients with traumatic eyelid injuries Patients with neoplastic lid disorders Pregnant, conceiving and lactating females history of any allergy to the study drugs Patients treated with oral or topical medications other than study drugs for posterior blepharitis within 3 months period

##### Intervention groups

1) Topical Azithromycin 1% twice daily for 1 week followed by once daily for 3 weeks 2) Oral Doxycycline 100 mg once daily for 4 weeks

##### Main outcome variables

1) Mean improvement in different symptoms score 2) Mean improvement in Schirmer 1 test 3) Mean improvement in Conjunctival hyperaemia 4) Mean

improvement in Corneal staining score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220607055097N3**

Registration date: **2022-08-30, 1401/06/08**

Registration timing: **retrospective**

Last update: **2022-08-30, 1401/06/08**

Update count: **0**

##### Registration date

2022-08-30, 1401/06/08

##### Registrant information

##### Name

Adnan Ahmad

##### Name of organization / entity

Nowshera Medical College, Nowshera

##### Country

Pakistan

##### Phone

+92 91 2586506

##### Email address

dradnanahmad@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-01, 1398/09/10

##### Expected recruitment end date

2021-01-01, 1399/10/12

##### Actual recruitment start date

2020-01-01, 1398/10/11

##### Actual recruitment end date

2020-06-01, 1399/03/12

**Trial completion date**

2020-08-01, 1399/05/11

**Scientific title**

Comparison of the efficacy of topical azithromycin with oral doxycycline in the treatment of meibomian gland dysfunction: A randomized clinical practice trial

**Public title**

Topical Azithromycin and oral doxycycline in meibomian gland dysfunction

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All the patients within the specified age group with posterior blepharitis secondary to meibomian gland dysfunction Patients with meibomian gland dysfunction, non responsive to conventional therapy such as lid massage, warm compresses and lid scrubbing

**Exclusion criteria:**

Patients with blepharitis other than posterior one Patients with other inflammatory lid conditions like atopic blepharoconjunctivitis Patients with traumatic eyelid injuries Patients with neoplastic lid disorders Pregnant, conceiving and lactating females history of any allergy to the study drugs Patients treated with oral or topical medications other than study drugs for posterior blepharitis within 3 months period

**Age**

From **26 years** old to **42 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization, unit of randomization taken as individual, non-stratified, Tools used in randomization was table of random numbers, allocation concealment was not carried out.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Prospective, randomized clinical practice trial

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Institutional Ethical Review Board of Nowshera Medical College

**Street address**

Mardan road, near Kabul river, Nowshera

**City**

Nowshera

**Postal code**

24110

**Approval date**

2019-11-20, 1398/08/29

**Ethics committee reference number**

0432 /R&D/IERB/NMC

**Health conditions studied**

1

**Description of health condition studied**

Meibomian gland dysfunction

**ICD-10 code**

H01.0

**ICD-10 code description**

Blepharitis

**Primary outcomes**

1

**Description**

Mean improvement in symptoms score

**Timepoint**

Baseline, 2nd and 4th week

**Method of measurement**

Subjective symptoms including itchy eyes, grittiness, MG plugging, foreign body (FB) sensation and watering were recorded in a check list as 0 = asymptomatic, 1= moderate and 2 = severe symptoms

2

**Description**

Mean improvement in corneal staining

**Timepoint**

Baseline, 2nd and 4th week

**Method of measurement**

For corneal staining, we divided the cornea into five regions and assigned a score of 1 for peripheral staining and 4 for staining of central cornea implying more severe involvement by the disease process.

3

**Description**

Mean improvement in bulbar conjunctival hyperaemia

**Timepoint**

Baseline, 2nd and 4th week

## Method of measurement

For bulbar conjunctival hyperaemia, area was divided into six regions and scoring from 0 to 4 was done depending upon the number of involved regions

## 4

### Description

Mean improvement in Schirmer 1 test

### Timepoint

Baseline, 2nd and 4th week

### Method of measurement

Schemers 1 test (5 min. test without anesthesia) were performed in all of the participants, > 10 mm wetting was considered as normal.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Topical Azithromycin 1%, Twice daily for 1 week followed by once daily for 3 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Oral Doxycycline 100 mg, once daily for 4 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Nowshera Medical College/ Qazi Hussain Ahmad Medical Complex

##### Full name of responsible person

Mubashir Rehman

##### Street address

Mardan road, near Kabul river, Nowshera

##### City

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##### Postal code

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##### Phone

+92 923 9220325

##### Email

drmubashirrehman78@gmail.com

##### Web page address

<https://nmcn.edu.pk/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Nowshera Medical College/ Qazi Hussain Ahmad Medical Complex

##### Full name of responsible person

Nizam Darwesh

##### Street address

Mardan road, near Kabul river, Nowshera

##### City

Nowshera

##### Postal code

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##### Email

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##### Web page address

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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

Nowshera Medical College/ Qazi Hussain Ahmad Medical Complex

#### 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

Nowshera Medical College, Nowshera

##### Full name of responsible person

Adnan Ahmad

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Ophthalmology

##### Street address

Civil colony

##### City

Peshawar

##### Province

Khyber Pukhtoonkhwa

##### Postal code

25000

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## Person responsible for scientific inquiries

**Contact**

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Nowshera Medical College, Nowshera

**Full name of responsible person**

Adnan Ahmad

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Nowshera Medical College, Nowshera

**Full name of responsible person**

Adnan Ahmad

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

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**City**

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**Province**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidential

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

IPD collected for the primary outcome measure only

**When the data will become available and for how long**

It will be available when published and up to 1 year after publication

**To whom data/document is available**

For people working in academic institutions

**Under which criteria data/document could be used**

For research and academic purposes

**From where data/document is obtainable**

Via email upon request

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

Request for access to data/document via email

**Comments**

Feel free to ask for any queries