Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 dysfuntion (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
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Pakistan
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nowshera Medical College/ Qazi Hussain Ahmad Medical Complex
Full name of responsible person
Nizam Darwesh
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Web page address
https://nmcn.edu.pk/
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
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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