# Evaluation of efficacy of moxifloxacin (0.5%) in the treatment of non-perforated bacterial corneal ulcers

| Submission date   | Recruitment status   | Prospectively registered       |
|-------------------|----------------------|--------------------------------|
| 30/06/2010        | No longer recruiting | Protocol                       |
| Registration date | Overall study status | Statistical analysis plan      |
| 11/08/2010        | Completed            | Results                        |
| Last Edited       | Condition category   | [] Individual participant data |
| 09/09/2010        | Eye Diseases         | [] Record updated in last year |

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Namrata Sharma

#### Contact details

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# Additional identifiers

Protocol serial number OP-19/07.09.2009

# Study information

Scientific Title

Evaluation of efficacy of moxifloxacin (0.5%) in the treatment of non-perforated bacterial corneal ulcers: a randomised controlled trial

## **Study objectives**

The use of fortified intensive antibiotics has practical limitations related to availability and cost. The effectiveness of multiple fortified antibiotics is limited further by variability in shelf life and the dissipation of 1 agent if a second agent is applied shortly thereafter. The use of multiple antibiotics simultaneously and with frequent dosing may result in added toxicity and damage to the ocular surface epithelium, thereby impairing recovery.

Fluoroquinolones offer the advantages of good ocular penetration, demonstration of broadspectrum efficacy, excellent safety profiles in ocular infections, and a distinct mode of resistance acquisition.

Moxifloxacin is a fourth-generation fluoroquinolone that exhibits a broad spectrum of bactericidal activity against both Gram-positive and Gram- negative bacterial pathogens, including staphylococci, S. pneumoniae, members of the family enterobacteriaceae, P. aeruginosa, H. influenzae, and Moraxella species. Moxifloxacin has also been shown to have superior activity compared with ciprofloxacin against quinolone resistant strains of S. aureus. Data also shows superior corneal and aqueous penetration of moxifloxacin and so higher therapeutic levels can be obtained, which should lead to more effective antimicrobials activity and hence better clinical outcomes.

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

The All India Institute of Medical Sciences Ethics Committee approved on the 4th August 2009 (ref: P-09/2.03.2009 & AA-04/04.08.2009)

## Study design

Prospective randomised controlled clinical trial

# Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Corneal ulcer

#### **Interventions**

Drug instillation protocol:

- 1. First 48 hours: 1 drop hourly, day and night
- 2. Day 3: 1 drop hourly by daya and every 2 hours at night
- 3. Days 4 5: 1 drop every 2 hours by day and every 4 hours by night
- 4. Days 6 7: 1 drop every 4 hours
- 5. Weeks 2 8: 1 drop every 6 hours and stopped when clinically appropriate

The total duration of treatment will be 8 weeks. Additional supportive treatment included vitamins, cycloplegic and antiglaucoma therapy if required. Any change of protocol, adverse event and surgical intervention was documented.

## **Intervention Type**

Drug

## **Phase**

Phase III

## Drug/device/biological/vaccine name(s)

Moxifloxacin

## Primary outcome(s)

- 1. Time to epithelialisation
- 2. Time to resolution of the infiltrates

All outcomes were measured on days 2, 4, 7, 14, 21 and at 3 months.

## Key secondary outcome(s))

- 1. Uncorrected Visual Acuity (UCVA)
- 2. Best Corrected Visual Acuity (BCVA)

All outcomes were measured on days 2, 4, 7, 14, 21 and at 3 months.

# Completion date

01/02/2010

# **Eligibility**

# Key inclusion criteria

Non-perforated bacterial corneal ulcers

# Participant type(s)

Patient

# Healthy volunteers allowed

No

## Age group

**Not Specified** 

#### Sex

All

## Key exclusion criteria

- 1. Known allergy to fluoroquinolones, aminoglycosides, penicillins,cephalosporins or benzalkoniun chloride
- 2. Patients with fungal, viral or acanthamoeba infection

- 3. Patients to be treated with subconjuctival injection(s) of antibiotic(s) and/or with systemic antimicrobials
- 4. Patients aged 16 65 years
- 5. Pregnant and lactating females
- 6. Any adverse effects or protocol violations
- 7. Perforated corneal ulcers

## Date of first enrolment

01/02/2009

## Date of final enrolment

01/02/2010

# Locations

## Countries of recruitment

India

Study participating centre Rajendra Prasad Centre for Ophthalmic Sciences New Delhi

New Delhi India 110029

# Sponsor information

## Organisation

Rajendra Prasad Centre for Ophthalmic Sciences (India)

### **ROR**

https://ror.org/02dwcqs71

# Funder(s)

# Funder type

Research organisation

#### Funder Name

All India Institute of Medical Sciences (AIIMS) (India)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes