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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 broad-spectrum 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)

Primary study design
Interventional

Study design
Prospective randomised controlled clinical trial

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
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