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Comparing the effectiveness of topical voriconazole versus injection of voriconazole and atamycin for recalcitrant fungal keratitis

Submission date
29/12/2011

Recruitment status
No longer recruiting

Registration date
10/01/2012

Overall study status
Completed

Last Edited
04/09/2014

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The first line of treatment for fungal corneal ulcers in the eye is natamycin eye. Generally such ulcers heal within 2 weeks. If they do not heal in 10-14 days another anti-fungal drug is used, such as voriconazole eye drops. However, the eye drops may not penetrate a deep lesion. Hence the aim of this study is to find out whether the injection of voriconazole into the eye is more effective than addition of another eye drop such as voriconazole in cases not responding to conventional antifungal therapy.

Who can participate?
Patients aged over 18 with fungal corneal ulcers not showing any signs of improvement after two weeks treatment with natamycin eye drops.

What does the study involve?
Participants will be randomly allocated into two groups. One group will be treated with voriconazole eye drops while the other group will be treated with voriconazole injections into the eye.

What are the possible benefits and risks of participating?
The benefits of enrolling are the treatment of the ulcer and the risks are slight pain and perforation of the ulcer. With both voriconazole eye drops and voriconazole injections there may be transient visual hallucinations which are reported rarely.

Where is the study run from?
Dr Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical Sciences (India).

When is study starting and how long is it expected to run for?
The study ran from December 2008 to June 2010.

Who is funding the study?
Dr Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical Sciences (India).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Comparative evaluation of topical versus intrastromal injection of voriconazole as an adjunct to natamycin in recalcitrant fungal keratitis: a randomised controlled trial

Study objectives
In cases of fungal keratitis who do not respond to natamycin, voriconazole is usually added. This can be given as topical eye drops or may be given in the form of injection. When injected intra-corneally, i.e. at the site of the lesion as targeted drug delievery , it may be be more effective. In addittion, the problems of compliance with topical eye drops are also addressed here.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical Sciences (AIIMS), India, 30/11/2008

Primary study design
Interventional

Study design
Randomized controlled clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fungal corneal ulcer, fungal keratitis

Interventions
Forty eyes of forty patients randomized into two groups of 20 patients each.

Group 1:
Topical 5% natamycin eye drops 4 hourly, 0.3% ciprofloxacin hydrochloride eye drops four times a day, 2% homatropine eye drops and 1% voriconazole eye drops prepared by ocular pharmacology by reconstituting injection voriconazole 200 mg powder in 19ml ringer lactate to instill 1 hourly round the clock for 48 hours followed by tapering of drug.

Group 2:
Patients randomized to intrastromal injections were taken to the operating room. Injection voriconazole 200mg powder reconstituted with Ringer lactate to obatin 50µg/0.1ml solution. Injections were repeated 72 hours apart. Patients in this group also received topical therapy with 5% natamycin 4 hourly, cycloplegics and 0.3% ciprofloxacin hydrochloride 6 hourly.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Atamycin, voriconazole

Primary outcome(s)
Best Spectacle Corrected Visual Acuity (BSCVA) 3 months after intervention.

Key secondary outcome(s)
Time to healing

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Patients with a smear or culture proven fungal ulcers
2. Ulcers greater than 2mm in size, involving more than one-third of the stromal thickness and not showing any signs of clinical improvement after two weeks of natamycin
3. Patients who were willing to be treated as an inpatient, willing to follow up regularly, and return for medications regularly every 48-72 hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with mixed infection on smear or culture, evidence of herpetic keratitis on history or examination, impending perforation, bilateral ulcers, those with vision less than 6/60 in the other eye, pre-existing scar not distinguishable from the new ulcer
2. Those less than 18 years of age

Date of first enrolment
01/12/2008

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
India

Study participating centre
Dr Rajendra Prasad Centre for Ophthalmic Sciences
New Delhi
India
110029

Sponsor information

Organisation
Dr Rajendra Prasad Centre for Ophthalmic Sciences (India)

ROR
https://ror.org/02dwcqs71

Funder(s)

Funder type

Research organisation

Funder Name
Dr Rajendra Prasad Centre for Ophthalmic Sciences (India)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration