

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

<b>Submission date</b> 29/12/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/09/2014	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Namrata Sharma, MD, DNB, MNAMS  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## 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 delivery, it may be more effective. In addition, 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

## **Study design**

Randomized controlled clinical trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **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 obtain 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 measure**

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

## **Secondary outcome measures**

Time to healing

## **Overall study start date**

01/12/2008

## **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

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

40

## **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)

**Sponsor details**  
All India Institute of Medical Sciences  
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+91 11 2659 3144  
namrata103@hotmail.com

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.aiims.edu/rpcentre.htm>

**ROR**  
<https://ror.org/02dwcqs71>

## **Funder(s)**

**Funder type**  
Research organisation

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

## **Results and Publications**

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration