

# Comparison of antibiotic-only and antibiotic-steroid combination treatment in corneal ulcer patients: a double-blinded, randomised clinical trial

<b>Submission date</b> 24/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/09/2009	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

Scientific Title

**Study objectives**

Null: There is no difference in residual ulcer size whether a corneal ulcer patient was treated with antibiotic alone or antibiotic with steroid.

Alternative: There is a significant difference in residual ulcers size between corneal ulcer patients treated with antibiotic alone and with antibiotic with steroid.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Corneal ulcers

**Interventions**

Antibiotic-only or Antibiotic-steroid combination treatment

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Residual ulcer size compared to baseline

**Key secondary outcome(s)**

1. Time to healing (days)
2. Rate of cure or treatment failure
3. Visual acuity
4. Quality of life
5. Physician Scoring of Ocular symptoms and signs

**Completion date**

14/09/2007

**Eligibility****Key inclusion criteria**

1. Bacterial corneal ulcer, defined as corneal epithelial defect and stromal inflammation of presumed bacterial origin, that is culture confirmed or gram stain positive
2. Involvement of only one eye
3. Over the age of 12 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Fungal, viral or amoebic keratitis
2. Known sensitivity or allergy to trial drugs
3. Perforated ulcer
4. Involvement of only functional eye, best corrected visual acuity worse than 20/200 in the uninfected eye
5. Use of topical or systemic steroids concurrently or within the past 2 months

**Date of first enrolment**

15/09/2005

**Date of final enrolment**

14/09/2007

**Locations****Countries of recruitment**

Canada

**Study participating centre**

Ottawa Hospital - General Campus

Ottawa, Ontario

Canada

K1H 8L6

**Sponsor information****Organisation**

Physicians' Services Incorporated Foundation (Canada)

**ROR**

<https://ror.org/0385yzn06>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Physicians' Services Inc (Canada)

## **Results and Publications**

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

**IPD sharing plan summary**

Not provided at time of registration