

# 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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Residual ulcer size compared to baseline

**Secondary outcome measures**

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

**Overall study start date**

15/09/2005

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

122

**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

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# Sponsor information

## Organisation

Physicians' Services Incorporated Foundation (Canada)

## Sponsor details

1006-5160 Yonge Street

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psif@psifoundation.org

## Sponsor type

Charity

## ROR

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

# Funder(s)

## Funder type

Charity

## Funder Name

Physicians' Services Inc (Canada)

# 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