

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

Submission date 24/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/09/2009	Condition category 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

Dr William Hodge

Contact details

Ottawa Hospital - General Campus
The University of Ottawa Eye Institute
501 Smyth Road
Ottawa, Ontario
Canada
K1H 8L6
+1 613 737 8218
whodge@ottawahospital.on.ca

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

K1H 8L6

Sponsor information

Organisation

Physicians' Services Incorporated Foundation (Canada)

Sponsor details

1006-5160 Yonge Street

North York, Ontario

Canada

M2N 6L9

+1 416 226 6323

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