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Comparison of the safety of two antibiotics - levofloxacin and cefuroxime - when they are used at the end of cataract surgery for the prevention of post-operative infection

Submission date 18/07/2009	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/07/2009	**Overall study status** Stopped	
Last Edited 27/08/2014	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SILC201109v2

Study information

Scientific Title

Comparison of the Safety of Intracameral Levofloxacin to intracameral Cefuroxime for the prevention of endophthalmitis in cataract surgery (SILC): a single-centre prospective double-blind randomised controlled trial

Acronym
SILC

Study objectives
There is no difference in the safety of intracameral levofloxacin and cefuroxime when used during cataract surgery for the prevention of endophthalmitis.

On 14/06/2010 this record was updated to reflect changes in the protocol from SILC201109 version 1 to version 2. All updates can be found in the relevant field with the above update date. Please also note that the start and end dates of this trial have been changed from 01/09/2009 and 01/08/2010 to 01/10/2010 and 01/10/2011, respectively. The target number of participants was changed from 36 to 30.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical research ethics committee, 23/03/2010

Primary study design
Interventional

Study design
Single-centre prospective double-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cataract surgery

Interventions
Participants requiring bilateral cataract surgery will be randomised firstly to receive cefuroxime or levofloxacin for their first eye surgery. Their fellow/second eye surgery will subsequently take place 5 weeks later. Follow-up for each eye following surgery will be one day after surgery, 3 weeks after surgery and 3 months after surgery for each eye. Following listing for cataract surgery and recuitment to the study there are a total of six out-patient appointments and two day surgery visits.

Drug administration:
Drug 1: Cefuroxime
Dose: 1 mg in 0.1 mL
Site of injection: Intracameral (i.e., into anterior chamber of eye)
Frequency of administration: single dose at end of cataract surgery

Drug 2: Levofloxacin
Dose: 500 µg in 0.1 mL

Site of injection: Intracameral (i.e., into anterior chamber of eye)
Frequency of administration: single dose at end of cataract surgery

Updated 27/08/2014: This study was abandoned in 2012 as levofloxacin is unlicensed for intraocular use and we never achieved MHRA/pharma consent despite 2 years of applications.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Levofloxacin, cefuroxime

Primary outcome(s)
Corneal endothelial cell count; a comparison will be made between pre-operative to post-operative results and between study groups (cefuroxime versus levofloxacin).

Key secondary outcome(s)
1. Visual acuity
2. Intra-ocular inflammation (flare and cells)
3. Corneal thickness
4. Macular thickness

These parameters will be compared from pre-operative to post-operative results and between study groups (cefuroxime versus levofloxacin).

Completion date
01/10/2011

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Patients undergoing routine cataract surgery attending the ophthalmology outpatient clinic at St Thomas' Hospital
2. Aged 20-100 years
3. Male or female (of non-childbearing potential)
4. Clinically normal corneal and retinal examination
5. Past ocular history - no history of long-term ocular condition, long-term use of ocular medications or ocular surgery
6. Ability to comply with investigation and follow-up schedule
7. Patients must give informed written consent in order to participate in the study. Non-English speakers will be offered an interpreter. All consents will be witnessed.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Unilateral cataract, very dense (brunescent or white) cataracts
2. Significant difference in corneal thickness, endothelial cell count/morphology or macular thickness of greater than 20% at baseline between the two eyes
3. Past ocular history in either eye of:
3.1. Pre-existing ocular conditions (glaucoma, retinal disease, uveitis, corneal disease)
3.2. Previous ocular surgery
3.3. Surgical complications in either eye
4. Diabetes requiring treatment
5. Medications: use of long-term topical eye drops with the exclusion of lubricant drops; use of tamsulosin (known to cause intra-operative floppy iris syndrome)
6. Allergies to fluoroquinolones, cephalosporins
7. Patients unable to give informed consent or are unable to understand the requirements of the trial

Date of first enrolment
01/10/2010

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Ophthalmology
London
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Sponsor information

Organisation
Guys' and St Thomas' Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
Guys' and St Thomas' Hospital NHS Foundation Trust (UK) - Funded internally

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration