The use of I-ZIP® Adherent Ocular Bandage to help cataract surgery incisions seal more effectively

Submission date	Recruitment status	Prospectively re	
09/07/2009	No longer recruiting	[] Protocol	
Registration date	Overall study status	[] Statistical analys	
04/09/2009	Completed	[X] Results	
Last Edited	Condition category	[] Individual partic	
31/01/2013	Eye Diseases		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

gistered

sis plan

ipant data

Secondary identifying numbers

Protocol 1, version 2

Study information

Scientific Title

The use of I-ZIP® Adherent Ocular Bandage to help cataract surgery incisions seal more effectively: a prospective consecutive randomised case-controlled study

Acronym

I-ZIP®

Study objectives

To determine whether I-ZIP® improves the sealing and architectural profile of clear cornear incisions and reduce the risks of leaking and endophthalmitis.

Ethics approval required

Old ethics approval format

Ethics approval(s) Berkshire Ethics Committee approved on the 9th June 2009 (ref: 09/H0505/35)

Study design Prospective consecutive randomised case-controlled study

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

Endophthalmitis/cataract surgery

Interventions

The methodology is identical for both arms, except for the application of the I-ZIP® bandage in the treatment arm, or not in the control arm. Both arms will receive clear corneal incision 2.2.mm wide micro coaxial phacoemulsification cataract surgery. The intraocular lens will be injected using C-cartridge and wound-assisted techniques. Patients will then be receive either the application of I-ZIP®, or not.

Within 1 hour of completing surgery: optical coherence tomography (OCT) examination Within 2 hours of completing surgery: slit lamp examination using 2% fluorescein and measurement of intraocular pressure (IOP)

Day 1 post-operative examination: OCT, slit lamp and IOP, slit lamp photograph Day 7 post-operative examination: OCT, slit lamp and IOP

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

Measured less than 1 hour, less than 2 hours, 1 day and 7 days post-operatively: 1. Optical Coherence Tomography (OCT) wound architecture 2. Intra-ocular pressure

Secondary outcome measures

No secondary outcome measures

Overall study start date 18/06/2009

Completion date

30/12/2009

Eligibility

Key inclusion criteria

- 1. Routine cataract surgery
- 2. 2.2 mm wide clear corneal incision
- 3. No wound enlargement
- 4. No stromal hydration of wound
- 5. Typical "older patient" of either sex, no specific age limits

Participant type(s) Patient

Age group Other

Sex Both

Target number of participants

50 patients - 25 patients treated with I-ZIP® and 25 patients in the control arm

Key exclusion criteria

1. Anterior segment ocular disease

2. Corneal endothelial dystropy

Complicated cataract surgery
Corneal suture

5. Stromal hydration required

Date of first enrolment 18/06/2009

Date of final enrolment 30/12/2009

Locations

Countries of recruitment England

United Kingdom

Study participating centre Department of Ophthalmology Windsor United Kingdom SL4 3DP

Sponsor information

Organisation Royal Berkshire NHS Foundation Trust (UK)

Sponsor details Research and Development Office Level 3, New Main Entrance Craven Road Reading England

United Kingdom RG1 5AN

Sponsor type Hospital/treatment centre

Website http://www.royalberkshire.nhs.uk/Default.aspx?theme=Patient

ROR https://ror.org/034nvrd87

Funder(s)

Funder type Industry

Funder Name I-Therapeutix, Inc. (USA)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Not provided at time of registrati

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2010		Yes	No