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

Submission date	Recruitment status	[_] Prospectively registered
09/07/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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

3. Complicated cataract surgery
4. 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

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