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

Submission date 09/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/09/2009	**Overall study status** Completed	
Last Edited 31/01/2013	**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
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)

Primary study design
Interventional

Study design
Prospective consecutive randomised case-controlled study

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Royal Berkshire NHS Foundation Trust (UK)

ROR
https://ror.org/034nvrd87

Funder(s)

Funder type
Industry

Funder Name
I-Therapeutix, Inc. (USA)

Results and Publications

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