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Validation of the BESSt Formula in eyes undergoing phacoemulsification following keratorefractive surgery

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 13/12/2013	**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
N0141187716

Study information

Scientific Title

Study objectives
To assess the feasibility of a randomised controlled trial to assess the accuracy of a formula (BESSt© formula) recently developed to calculate the power of the lens to implant in the eye during cataract surgery in eyes which have previously undergone laser refractive surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Centrally randomised controlled trial - pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Eye Diseases: Cataract

Interventions
1. BESSt©
2. Hollday

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Patient recruitment rates
2. Rates of loss to follow up in treatment arm
3. Difference between target and achieved manifest refraction following phaci in the two groups

Key secondary outcome(s)
Proportion of eyes with outcomes within +0.25/0.5/0.75/1/1.50/2.0D from the target refraction using the different formulae

Completion date
01/05/2007

Eligibility

Key inclusion criteria
1. Any eye undergoing phaco following keratorefractive surgery
2. Any intraocular lens (IOL) model

3. Any type of keratorefractive surgery
4. Patients under the care of Ms Ficker or Mr Stevens

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Children
2. Corneal scarring or opacity
3. Severe dry eyes or ptosis
4. Complicated phaco, presence of a rhexis tear if IOL is implanted in bag

Date of first enrolment
01/08/2006

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Moorfields Eye Hospital
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Moorfields Eye Hospital NHS Foundation Trust

Funder Name
NHS R&D Support Funding

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	01/12/2006		Yes	No