ISRCTN34442493 https://doi.org/10.1186/ISRCTN34442493

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

Contact name
Dr Edmondo Borasio

Contact details
Moorfields Eye Hospital
162 City Road
London
United Kingdom
EC1V 2PD
edmondoborasio@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Centrally randomised controlled trial - pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
1. BESSt©
2. Hollday

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/08/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
30 eyes

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Moorfields Eye Hospital NHS Foundation Trust

Funder Name
NHS R&D Support Funding

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	01/12/2006		Yes	No