

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/12/2013	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

**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**  
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 rhegms 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  
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+44 (0)20 7307 2622  
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### **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?
<a href="#">Results article</a>	results	01/12/2006		Yes	No