

# Randomised trial of four to six week follow ups vs no medical follow up after uncomplicated cataract extraction

<b>Submission date</b> 05/02/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/05/2019	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

At the moment, most patients who have cataract surgery visit the eye clinic 4-6 weeks after their operation. Some doctors would say that this is not necessary, as the eye will usually have healed very well by this time. We would like to conduct a study to check that discharging certain patients immediately after their cataract surgery is safe. We would only discharge those patients in whom cataract surgery was straightforward, and those patients with no other eye problems. This would cut down on unnecessary visits to the eye clinic. Advice and assessment for any problems or concerns after the surgery would of course still always be available by contacting the eye clinic as usual.

### Who can participate?

Participants will be patients who have a routine cataract operation in the near future.

### What does the study involve?

Patients are randomly allocated to one of two groups: one group visits the clinic after the operation and the other doesn't. The study involves some questionnaires during the study. These include questionnaires relating to the quality of life of the patient (conducted before the operation and at the 3-month research clinic) and a patient satisfaction questionnaire. There is also a research clinic 3 months following the operation.

### What are the possible benefits and risks of participating?

There are no real personal benefits to participating patients. The study aims to provide very important information regarding the safety of discharging patients immediately after surgery. However, the study could potentially save many thousands of unnecessary hospital visits each year. The vast majority of patients who undergo cataract surgery have a good result whether they are followed up in clinic or not. There is only a very small chance of a post-operative problem not being picked up regardless of whether there is follow up or not. Serious problems following such procedures are rare and they are usually obvious to the patient as they generate

new symptoms. Should any serious complication occur the patient will be able to attend eye clinic to receive guidance or treatment. Patients in the study are able to contact the eye clinic for advice or to request a clinic appointment.

Where is the study run from?

Torbay District General Hospital, UK.

When is the study starting and how long is it expected to run for?

The study started in February 2014 and is expected to last for 2 years.

Who is funding the study?

Torbay Medical Research Fund (UK).

Who is the main contact?

Mr Andrew Frost

Phone: +44 (0)1803 656635

Email: [sdhct.research@nhs.net](mailto:sdhct.research@nhs.net)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Andrew Frost

### Contact details

C/O Research and Development Department

Torbay District General Hospital

Lawes Bridge

Torquay

United Kingdom

TQ2 7AA

+44 (0) 1803 656635

[sdhct.research@nhs.net](mailto:sdhct.research@nhs.net)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02071147

Secondary identifying numbers

14/02/050

## Study information

**Scientific Title**

Randomised trial of four to six week follow ups vs no medical follow up after uncomplicated cataract extraction

**Study objectives**

Is it safe to discharge patients straight to their optometrist following routine cataract extraction rather than reviewing them in the hospital eye clinic post-operatively?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee South West - Frenchay; 18/12/2013; ref. 13/SW/0318

**Study design**

Single-centre two arms randomised single-blinded (nurse-blinded) study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**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**

Eyes Cataract extraction

**Interventions**

Pathway 1 (standard clinical intervention): Patients reviewed at 6 weeks (+/- 1 week) as is our normal practice and recalled for a further evaluation if deemed appropriate. Patients will be instructed to visit their optometrist once their eye has fully recovered from the operation for provision of glasses.

Pathway 2 (No clinical follow up): No routine follow-up appointment is made. Patients will be instructed to visit their optometrist between 6-8 weeks post-operative for review of the patient's glasses.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. The primary outcome is corrected distance visual acuity (VA). The primary end point will be VA after 3 months of follow up
2. The primary outcome vision-related quality of life impairment measures are the VCM1 and catquest questionnaires after 3 months of follow up

**Secondary outcome measures**

1. Post-operative complication rate difference between the two groups
2. Post-operative patient satisfaction between the two groups at 3 months

**Overall study start date**

03/02/2014

**Completion date**

01/12/2015

**Eligibility****Key inclusion criteria**

1. Adults aged  $\geq 40$  years
2. Scheduled for day-case cataract surgery
3. Able to give informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

400

**Key exclusion criteria**

1. Unable to provide written informed consent
2. Unable to visit their optometrist post-operatively
3. Patients with ocular comorbidity that may be affected by cataract surgery or who require monitoring within 3 months of their operation (including significant diabetic retinopathy, wet age-related macular degeneration (AMD) on treatment, severe/end stage glaucoma, previous retinal detachment or vitrectomy)
4. Patients undergoing another simultaneous ophthalmic procedure
5. Patients who suffer from an intra-operative complication requiring early post-operative evaluation (identified at surgery)

**Date of first enrolment**

03/02/2014

**Date of final enrolment**

01/12/2015

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

C/O Research and Development Department,  
Torquay  
United Kingdom  
TQ2 7AA

## **Sponsor information**

**Organisation**

South Devon Healthcare NHS Foundation Trust (UK)

**Sponsor details**

R&D Manager,  
Research & Development Department,  
Horizon Centre,  
Torbay District General Hospital,  
Lawes Bridge  
Torquay  
England  
United Kingdom  
TQ2 7AA  
+44 (0) 1803 656635  
sdcht.research@nhs.net

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05374b979>

## **Funder(s)**

**Funder type**

Research organisation

### Funder Name

Torbay Medical Research Fund (UK)

## 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="#">HRA research summary</a>			28/06/2023	No	No