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

Submission date	Recruitment status	[ ] Prospectively registered
05/02/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/04/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/05/2019	Eye Diseases	[ ] 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 doesnt. 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?
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Contact information

Type(s)
Scientific

Contact name
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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 >= 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
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Sponsor information

Organisation
South Devon Healthcare NHS Foundation Trust (UK)

Sponsor details
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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?
HRA research summary			28/06/2023	No	No