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Health of Patients' Eyes in Glaucoma Clinics: HOPE Glaucoma

Submission date	Recruitment status	[_] Prospectively registered
22/08/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/08/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/02/2017	Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14767

Study information

Scientific Title
Health of Patients' Eyes in Glaucoma Clinics: HOPE Glaucoma

Acronym
HOPE Glaucoma

Study objectives
Glaucoma involves progressive optic nerve fibre loss, subsequently leading to irreversible and disabling visual field defects. In the UK alone, more than 200,000 patients have this condition. Glaucoma patients need to be followed-up periodically, which means it is a large financial and resource burden to the NHS. Glaucoma has a history of poor therapy adherence and lack of patient knowledge of their condition if frequently cited as a cause (Grey et al. 2010). In this study the aim is to assess whether providing patients with a client-held eye health summary (a personal record of their condition) improves patients' knowledge about their disorder and subsequently has a beneficial impact on the rate of deterioration of their eye(s). The hypothesis is that improved disease knowledge, through the introduction of a fairly simple and cheap patient-held tool, improves awareness and contributes to positive behavioral change in patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 28/09/2012, ref: 12/YH/0471

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Eye; Subtopic: Eye (all Subtopics); Disease: Glaucoma

Interventions
Not provided at time of registration

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/06/2013

Completion date
10/06/2014

Eligibility

Key inclusion criteria
1. Adult (age > 18 years)
2. Patients diagnosed with glaucoma, to include the following three diseases:
2.1. Ocular Hypertension (OHT): Intra ocular pressures raised above the normal range (more than or equal to 21 mmHg), but no signs of optic nerve fibre loss or visual field loss
2.2. Suspected glaucoma (SG): Optic nerve fibre loss or visual field loss of both in presence of normal intraocular pressures
2.3. Chronic Open Angle Glaucoma (COAG): Any combination of raised intraocular pressures, optic nerve fibre loss and/or visual field loss
Target Gender: Male & Female; Upper Age Limit 100 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 122; UK Sample Size: 122

Key exclusion criteria
1. Under age (< 18 years)
2. Mental incapacity through inability to read, co-morbidities (e.g. severe stroke, advanced dementia) or any other contributing factor

3. Inability to provide informed written consent
4. Unable to speak or understand English since interpreter is not available throughout the course of the study

Date of first enrolment
10/06/2013

Date of final enrolment
10/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cumberland Infirmary
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
North Cumbria University Hospitals NHS Trust (UK)

Sponsor details
West Cumberland Hospital
Hensingham Whitehaven
Cumbria
England
United Kingdom
CA28 8JG

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
International Glaucoma Association (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?
Protocol article	protocol	07/08/2015		Yes	No
Results article	results	30/08/2017		Yes	No