

Health of Patients' Eyes in Glaucoma Clinics: HOPE Glaucoma

Submission date 22/08/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/02/2017	Condition category 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
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 is 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