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Adherence to therapy for patients with glaucoma or ocular hypertension

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 11/04/2017	**Condition category** Eye Diseases	

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
N0453168857

Study information

Scientific Title
Adherence to therapy for patients with glaucoma or ocular hypertension

Study objectives
Current hypothesis as of 03/04/2008:
An individualised programme of care can improve adherence to therapy in newly treated cases of glaucoma or ocular hypertension

Previous hypothesis:
To establish the effect of enhanced nursing input to the persistency of therapy in newly treated cases of glaucoma and ocular hypertension.

Please note that the trial title was "The impact of enhanced nursing input on persistency of therapy in newly treated cases of glaucoma and ocular hypertension" until April 2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Manchester Local Research Ethics Committee, 20/12/2004, amendment approved on 15 /06/2005

Study design
Two-arm pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
Eye Diseases: Glaucoma

Interventions
Added April 2008:

This pilot study has three parts.

Part 1: A Cochrane Systematic Review entitled, Interventions for improving adherence to ocular hypotensive therapy. Protocol for the Cochrane review published on: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD006132/pdf_fs.html

Part 2: A cross-sectional study to collect baseline data entitled, Factors associated with poor adherence to ocular hypotensive therapy. Data will be collected via observation and interview from the outpatient clinic of the host organisation for patients diagnosed with glaucoma or ocular hypertension. This will include:
2.1 Observation of clinical practice in relation to verbal and written information regarding the use of eye drops and follow-up care, adherence to therapy advice and eye drop training.
2.2 Face to face interviews with patients to establish their knowledge of glaucoma, daily eye care management and problems associated with managing eye drops. Adherence to therapy will also be measured.

Part 3: A two-arm randomised controlled trial entitled the impact of an individualised programme of care on persistence of and adherence to therapy in newly treated cases of glaucoma or ocular hypertension. Stratification will take place on the basis of the type of clinic patients attend.
In arm 1 (non-intervention arm) patients will continue to receive the information, advice and training they would normally be given at the host organisation.
In arm 2 (intervention arm), patients will, in addition, undergo an assessment by a research nurse that takes into account factors such as other medical conditions, additional medications, independence with daily living activities, potential problems managing an eye drop regime and beliefs about medications etc.
Patients will receive a detailed explanation of the importance of therapy adherence, training on eye-drop instillation techniques and handouts giving further information about glaucoma or ocular hypertension. An individualised programme of care will be developed for each patient; this will include a series of follow-up contacts to ensure that the patient is managing their eye-drops and that any issues regarding adherence are dealt with promptly. All included patients will continue to follow the normal treatment protocols of the host organisation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Persistency of treatment during the first year of therapy will be the main outcome measure. Persistency will be measured by comparing the number of doses dispensed and the number prescribed, taking into account that UK prescriptions are valid for 28 days.

Secondary outcome measures
Added April 2008:
Adherence to therapy, illness perceptions, beliefs about medicines and patient enablement. Secondary outcomes will be measured via validated questionnaires during patient interviews at the end of the study.

Overall study start date
21/04/2005

Completion date
31/07/2011

Eligibility

Key inclusion criteria
Added April 2008:
Patients newly prescribed ocular hypotensive eye drops with a diagnosis of open angle glaucoma, normal tension glaucoma, pseudo-exfoliation glaucoma, pigment dispersion glaucoma or ocular hypertension.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 - 60 patients in each arm.

Key exclusion criteria
Added April 2008:
Patients unable to give informed consent or patients already prescribed a complicated drop regime for another eye condition.

Date of first enrolment
21/04/2005

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
REH Central Manchester & Manchester Children's University Hospitals
Manchester
United Kingdom
M13 9WH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Central Manchester and Manchester Children's University Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding (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