# Adherence to therapy for patients with glaucoma or ocular hypertension

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

### Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

Prof David B Henson

### Contact details

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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 +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

### 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