

Helping adherence with glaucoma treatment: a randomised trial

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/09/2014	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
6798

Study information

Scientific Title

A single centre randomised interventional trial of additional education and advice about glaucoma versus standard care in improving adherence with topical anti-glaucomatous therapy

Acronym

Adherence study

Study objectives

To determine whether additional education and advice about glaucoma and its management, over and above standard care, is beneficial and cost-effective in improving adherence with topical anti-glaucomatous therapy.

As of 22/12/2010 this record was extensively updated; all changes can be found in the relevant field with the above update date. At this time, the anticipated end date was extended from 22/11/2010 to 22/11/2011.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved on the 19th February 2008 (ref: 08/H0310/11)

Study design

Single centre randomised interventional process of care trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

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

Topic: Eye, Primary Care Research Network for England; Subtopic: Not Assigned, Eye (all Subtopics); Disease: Ophthalmology, All Diseases

Interventions

The Education and Support intervention will be delivered by four GSAs using motivational interviewing techniques.

Added 22/12/2010:

Duration of follow-up is 8 months. Intervention not disclosed due to masking of physicians working within the department.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Percentage adherence rate compared between control and intervention group.

Added 22/12/2010:

Outcome measures are recorded at 2 months and 8 months post-randomisation.

Secondary outcome measures

1. Correlate the level of self-reported adherence with actual adherence and determine associative factors
2. Identify the demand for specific components of the glaucoma support intervention
3. Identify predictors of the level of adherence

Added 22/12/2010:

Outcome measures are recorded at 2 months and 8 months post-randomisation.

Overall study start date

23/11/2009

Completion date

22/11/2011

Eligibility

Key inclusion criteria

Added 22/12/2010:

1. Newly diagnosed or previously untreated glaucoma patients and ocular hypertension patients prescribed Travoprost
2. Over 18 years old, no upper age limit
3. Male and female

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 200

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

23/11/2009

Date of final enrolment

22/11/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Norfolk and Norwich University Hospital NHS Trust

Norwich

United Kingdom

NR4 7UY

Sponsor information

Organisation

Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

Sponsor details

Colney Lane

Colney

Norwich

England

United Kingdom

NR4 7UY

Sponsor type

Hospital/treatment centre

Website

<http://www.nnuh.nhs.uk>

ROR

<https://ror.org/01wspv808>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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	22/11/2012		Yes	No
Results article	results	24/03/2014		Yes	No