Helping adherence with glaucoma treatment: a randomised trial

Submission date	Recruitment status No longer recruiting	Prospectively registered	
12/05/2010		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
12/05/2010	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
26/09/2014	Eye Diseases		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Heidi Cate

Contact details

Norfolk and Norwich University Hospital NHS Trust Glaucoma Research Unit Norwich United Kingdom NR4 7UY

Additional identifiers

Protocol serial number

6798

Study information

Scientific Title

A single centre randomised interventional trial of additional education and advice about glaucoma verus 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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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)

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

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?
Results article	results	24/03/2014	Yes	No
<u>Protocol article</u>	protocol	22/11/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes