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Medium/long term effect of travoprost on the intraocular pressure (IOP) in normal tension glaucoma (NTG)

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 03/06/2008	**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
N0547147995

Study information

Scientific Title

Study objectives
Travoprost is a new prostaglandin analogue recently approved for treatment of ocular hypertension and glaucoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
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

Health condition(s) or problem(s) studied
Eye Diseases: Glaucoma

Interventions
Prospective randomised controlled observer blinded clinical trial.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary clinical outcome measure is diurnal IOP at follow up phasing: the major comparison is to be made between the IOP for travoprost treatment group and for the non-treatment group.

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/04/2004

Completion date
01/06/2006

Eligibility

Key inclusion criteria
Adults with normal tension glaucoma.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
25-30 patients

Key exclusion criteria
1. Patients on systemic medication
2. Patients who have undergone intraocular eye surgery

Date of first enrolment
01/04/2004

Date of final enrolment
01/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Senior House Officer
Norwich
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
East Norfolk and Waveney Research Consortium - Norfolk and Norwich University Hospital /Norwich PCT

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?
Results article	Results	01/08/2008		Yes	No