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The United Kingdom Glaucoma Treatment Study

Submission date 11/10/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/12/2006	**Overall study status** Completed	
Last Edited 14/02/2018	**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
06-Q0406-27

Study information

Scientific Title
The United Kingdom Glaucoma Treatment Study

Acronym
UKGTS

Study objectives
The proposed study is a randomised, double-masked, placebo-controlled treatment study to demonstrate the effectiveness of latanoprost in reducing the frequency of progression events compared to placebo-treated eyes (primary outcome).

The main secondary outcomes of the study are the identification of risk factors for progressive glaucoma and an evaluation of measurements of the rate of progression of glaucoma by measurement of optic nerve head (ONH) and retinal nerve fibre layer (RNFL) structure with quantitative imaging technology, and of visual function with conventional perimetry. It is anticipated that the use of rates of progression will enable improved study designs for subsequent clinical trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hammersmith and Queen Charlotte's & Chelsea Research Ethics Committee, 01/06/2006, REC ref: 06/Q0406/27

Study design
Randomised double-masked placebo-controlled treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Glaucoma

Interventions
Eligible patients will be randomised to one of two treatment arms:
1. Latanoprost for 18 months
2. Placebo for 18 months

It is anticipated that enrolment will take one year, giving a total study duration of 30 months. Patients reaching a safety endpoint will cross over into the treated arm and continue to be followed. A data monitoring committee will be set up to review study safety and progress.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Latanoprost

Primary outcome measure
The effectiveness of Latanoprost in reducing the frequency of progression events compared to placebo-treated eyes.

Secondary outcome measures
1. The identification of risk factors for progressive glaucoma
2. An evaluation of measurements of the rate of progression of glaucoma by measurement of ONH and RNFL structure with quantitative imaging technology, and of visual function with conventional perimetry.

It is anticipated that the use of rates of progression will enable improved study designs for subsequent clinical trials.

Overall study start date
01/11/2006

Completion date
31/10/2009

Eligibility

Key inclusion criteria
1. Newly detected, previously untreated open-angle glaucoma (including primary open-angle glaucoma, normal tension glaucoma and pseudoexfoliation glaucoma) in either eye. Glaucoma is defined as: reproducible glaucomatous visual field (VF) defects in at least one eye with corresponding damage to the optic nerve head (cup disc ratio more than or equal to 0.7 and/or focal narrowing of the neural rim) and in the absence of retinal or neurological condition that may account for the VF loss. A glaucomatous VF is defined as a reproducible defect (in at least two consecutive reliable post-screening VFs) of two or more contiguous points with P less than 0.01 loss or greater, or three or more contiguous points with P less than 0.05 loss or greater, or a 10-dB difference across the nasal horizontal midline at two or more adjacent points in the total deviation plot. Note: this differs from the Early Manifest Glaucoma Treatment (EMGT) criteria - Glaucoma Hemifield Test (GHT) outside normal limits in the same sector on two consecutive tests performed on different days, or GHT Borderline in the same sector on two consecutive tests performed on different days and obvious localised glaucomatous changes of the optic disc in an area corresponding to the field defect
2. Intraocular pressure: mean (screening and training visit) less than 30 mmHg, any intraocular pressure (IOP) less than 35 mmHg
3. Age: adult over 18 years (note: this differs from EMGT where the age range was 50 to 80 years of age)
4. Snellen visual acuity equal to or better than 6/12

5. Able to give informed consent and attend at the required frequency for the duration of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
686 in total

Key exclusion criteria
1. Moderately advanced visual field loss (mean deviation worse than -10dB in the better eye or worse than -16 dB in the other eye) or a threat to fixation (paracentral point total sensitivity less than 10 dB) in either eye (note: EMGT had no extra criteria for paracentral points)
2. Intraocular pressure more than 35 mmHg on two consecutive occasions in either eye
3. Unable to perform reliable visual field testing (less than 15% false positives, less than 20% fixation losses)
4. Unable to provide sufficient quality Heidelberg Retina Tomograph (HRT) images (mean pixel height standard deviation [MPHSD] less than 40 µm)
5. Cataractous lens gradings of more than N1, C2, or P1 according to Lens Opacities Classification System III (LOCS III)
6. Previous intraocular surgery (other than uncomplicated cataract extraction with posterior chamber lens implantation)
7. Cataract extraction with posterior chamber lens implantation within the last year
8. Diabetic retinopathy

Date of first enrolment
01/11/2006

Date of final enrolment
31/10/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Moorfields Eye Hospital
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

Sponsor details
162 City Road
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Sponsor type
Hospital/treatment centre

Website
http://www.moorfields.nhs.uk/Home

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Industry

Funder Name
Pfizer Pharmaceuticals (UK) - unresticted grant

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	01/01/2013		Yes	No
Results article	results	01/12/2013		Yes	No
Results article	results	04/04/2015		Yes	No
Results article	results	01/09/2015		Yes	No
Results article	results in :	01/01/2018		Yes	No