

The United Kingdom Glaucoma Treatment Study

Submission date 11/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/02/2018	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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised double-masked placebo-controlled treatment trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Moorfields Eye Hospital

London

United Kingdom

EC1V 2PD

Sponsor information

Organisation

Moorfields Eye Hospital NHS Foundation Trust (UK)

ROR

<https://ror.org/03zaddr67>

Funder(s)

Funder type

Industry

Funder Name

Pfizer Pharmaceuticals (UK) - unrestricted grant

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	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
Protocol article	protocol	01/01/2013		Yes	No