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A comparative study of the efficacy and tolerance of three antiglaucoma prostaglandin analogue eyedrops (Latanoprost, Travoprost and Bimatoprost)

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
17/02/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
N0249122172

Study information

Scientific Title

Study objectives
What is the relative efficacy and tolerance of three prostaglandin analogue eyedrops?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Informed consent was obtained from all patients. The study was approved by the local Research Ethics Committee (Somerset Research Ethics Committee) and the Medicines and Healthcare products Regulatory Agency, UK and was run in accordance with the principles of Good Clinical Practice (Helsinkis declaration).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Eye Diseases: Glaucoma

Interventions
1. Latanoprost
2. Travoprost
3. Bimatoprost

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
prostaglandin: Latanoprost, Travoprost, Bimatoprost

Primary outcome measure
Added March 2008:
A comparison of the efficacy, in terms of intra-ocular pressure reduction.

Secondary outcome measures
Added March 2008:
A comparison of the tolerance profile.

Overall study start date
01/02/2003

Completion date
31/10/2006

Eligibility

Key inclusion criteria
Added March 2008:
Newly diagnosed patients with ocular hypertension, open angle glaucoma (including primary open angle glaucoma, pseudo-exfoliation and pigment dispersion syndrome) or normal tension glaucoma.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
120 patients

Key exclusion criteria
Added March 2008:
1. Patients <20 years
2. Pregnancy
3. Intraocular pressure (IOP) of 40 mmHg or more
4. Severe visual field loss or scotoma within 5° of fixation
5. Patients with secondary glaucoma
5. History of intraocular surgery in the preceding year
6. Prostaglandin derivative was contraindicated

Date of first enrolment
01/02/2003

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ophthalmology Department
Taunton
United Kingdom
TA1 5DA

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Taunton and Somerset NHS Trust (UK)

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	01/10/2010		Yes	No