

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/02/2011	Condition category Eye Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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
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 (Helsinki declaration).

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

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(s)

Added March 2008:

A comparison of the efficacy, in terms of intra-ocular pressure reduction.

Key secondary outcome(s)

Added March 2008:

A comparison of the tolerance profile.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Ophthalmology Department

Taunton

United Kingdom
TA1 5DA

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Taunton and Somerset NHS Trust (UK)

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	01/10/2010		Yes	No