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Effects of bimatoprost and latanoprost on ocular hemodynamics in normal tension glaucoma: a randomised trial

Submission date	Recruitment status	[_] Prospectively registered
09/03/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2008	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
1723427327/3

Study information

Scientific Title

Study objectives
It is hypothesised that locally applied prostaglandins improve ocular haemodynamics in normal tension glaucoma patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was performed in accordance to institutional, national, and international guidelines and was approved by the local ethics committee.

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
Normal tension glaucoma

Interventions
Administration of latanoprost or bimatoprost eye drops.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bimatoprost, latanoprost

Primary outcome measure
Ocular perfusion is assessed by Doppler imaging. Primary endpoints are the peak systolic velocity (PSV) and end-diastolic velocity (EDV) in the short posterior ciliary artery.

Secondary outcome measures
Secondary endpoints are:
1. The PSV and EDV in:
1.1. The long posterior ciliary artery,
1.2. The central retinal artery, and
1.3. The ophthalmic artery
2. Resistivity index, pulsatility index and time average velocity (maximum and mean) in all four vessels
3. Intraocular pressure

Overall study start date
01/01/2003

Completion date
31/12/2003

Eligibility

Key inclusion criteria
Progressive normal tension glaucoma patients. Progression was defined as progressive excavation of the optic disc (funduscopic and controlled by the Heidelberg retina tomography [HRT]) and/or progressive visual field loss in the Humphrey perimeter over the last 6 - 12 months.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Treated open angle glaucoma
2. Intraocular pressure greater than 21
3. Non-compliance

Date of first enrolment
01/01/2003

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
Germany

Study participating centre
Martinistr. 52
Hamburg
Germany
20246

Sponsor information

Organisation
University Medical Center Hamburg-Eppendorf (Germany)

Sponsor details
Martinistr. 52
Hamburg
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D-20246

Sponsor type
University/education

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
University/education

Funder Name
University Medical Center Hamburg-Eppendorf (Germany)

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	05/04/2005		Yes	No