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Comparison of the Clinical Efficacy and Tolerability of Latanoprost RDR Eye Drops vs. Xalatan® Eye Drops for the Treatment of Ocular Hypertension and Primary Open Angle Glaucoma

Submission date 29/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/11/2010	**Overall study status** Completed	
Last Edited 11/08/2011	**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

Clinical Trials Information System (CTIS)
2008-002122-10

Protocol serial number
RDR 342; EudrCT-Number: 2008-002122-10

Study information

Scientific Title
Comparison of the Clinical Efficacy and Tolerability of Latanoprost RDR 0.005% Eye Drops Test Formulation of RDR Pharma GmbH, Germany, for the Treatment of Ocular Hypertension and Primary Open Angle Glaucoma with Xalatan® 0.005% Eye Drops: A multicenter, randomized, investigator-blind clinical trial with parallel groups

Acronym
RDR 342

Study objectives
The study drug is tested for non-inferiority in comparison to Xalatan®

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the State of Berlin, State Office of Health and Welfare (Ethik-Kommission des Landes Berlin, Landesamt für Gesundheit und Soziales [LAGeSo]) approved on the 17th of October 2008 (ref: ZS EK 14 280/08)

Study design
Prospective multicentre two arm randomised investigator blind parallel group clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ocular Hypertension; Primary Open Angle Glaucoma

Interventions
Test Drug: Latanoprost 0.005% RDR Eye Drops
Reference Drug: Xalatan® 0.005% Eye Drops

Patients are randomised to receive either the test drug or the reference drug. Dose, duration, frequency and mode of application is the same for both:
Dose: 1 drop
Duration: 42 days
Frequency: once a day
Mode of application: The drug is to be dropped into the affected eye(s)

Possible Interim Drugs (for patients treated with prostaglandins or betablockers at baseline, undergoing a 4 week washout period)
Dorzolamide-containing eye-drops (20 mg/ml), or
Pilocarpine-containing eye-drops (20 mg/ml)
The interim drug may be described by the Investigator for a period of three weeks. The interim

drug should be stopped one week or 3 days, respectively, before the baseline investigation and start of study medication. For either medication:
Dose: 1 drop
Frequency: 3 times a day

Duration of the study is up to 10 weeks for subjects (6 weeks treatment, + 4 weeks wash out phase only if necessary), with 4 visits including initial screening/consenting visit.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Intra-ocular pressure:
Mean change of the 8 am IOP from baseline value to end of study value measured on the study eye

Key secondary outcome(s))
1. Efficacy
1.1. Mean change of the 8am IOP from baseline value to visit 2
1.2. Mean change of the 12noon and 4pm IOP from baseline value to visit 2 and to end of study value

2. Safety
2.1. Adverse Events
2.2. Subjective tolerance
2.3. Ophthalmologic examinations
2.4. Vital signs

Completion date
10/12/2009

Eligibility

Key inclusion criteria
1. Unilateral or bilateral ocular hypertension or primary open angle glaucoma at an early stage
2. In at least one eye, IOP ≥ 22 mmHg at 8am and IOP ≤ 30 mmHg at 8 am, 12 noon and 4 pm under the following conditions:
2.1. untreated ocular hypertension, or
2.2. 4 week washout period of an initial monotherapy with a prostaglandin or beta-blocker
3. Best corrected visual acuity ≥ 20/100 (Snellen) or 2/10 (Monoyer)
4. Male and female patients, age ≥ 18 years
5. Female subjects of childbearing age must be using a medically accepted form of birth control and must have a negative urine pregnancy test at screening
6. Able to provide informed consent after risks and benefits of the study have been explained
7. Ability to communicate effectively with study personnel
8. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. In both eyes, IOP < 22 mmHg
2. IOP > 30 mmHg
3. Known sensitivity to latanoprost or any component of the drug products
4. Use of contact lenses
5. Other defined ocular diseases, ocular interventions, or ocular medications
6. Pregnancy or breastfeeding
7. Other defined diseases such as dysfunction of the liver or the kidneys, cancer, angina pectoris, asthma bronchiale, haematological diseases
8. Current or anamnestic drug addiction or extensive alcohol use
9. Participation in another clinical study within 4 weeks prior to enrolment
10. History of non-compliance
11. Any condition that compromises the ability to understand or comply with study requirements
12. Committed to an institution by virtue of an order issued either by the judicial or the administrative authorities

Date of first enrolment
25/05/2009

Date of final enrolment
10/12/2009

Locations

Countries of recruitment
Bulgaria

Germany

Latvia

Poland

Study participating centre

Kurfürstendamm Nr 69
Berlin
Germany
10707

Sponsor information

Organisation
RDR Pharma GmbH (Germany)

Funder(s)

Funder type
Industry

Funder Name
Bausch & Lomb GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration