# 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

Recruitment status	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Last EditedCondition category11/08/2011Eye Diseases	Record updated in last year
	No longer recruiting  Overall study status  Completed  Condition category

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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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  $\geq$  22 mmHg at 8am and IOP  $\leq$  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  $\geq 20/100$  (Snellen) or 2/10 (Monoyer)
- 4. Male and female patients, age  $\geq$  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 mmHa
- 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes