Title

A comparison of latanoprost 50 g/ml eye drops vs. Xalatan™ eye drops in the treatment of open angle glaucoma: an open, randomized, clinical trial

Protocol code

QTM/OMN0111

EudraCT number

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Sponsor

Omnivision GmbH

Lindberghstr. 9

82178 Puchheim

Tel: (+49) 089/ 840 79 230

Fax: (+49) 089/ 840 79 240

Clinical investigation design

This is a Phase III, open with a blinded observer, randomized clinical trial with two parallel groups to evaluate the efficacy and safety of Latanoprost 50 µg/ml eye drops in comparison with that of a commercial Latanoprost eye drops (Xalatan™, Pfizer) in the relief of open angle glaucoma.

Treatments administered

Investigational Drug: Latanoprost, one drop administered topically in the eye once daily for 28 days.

Reference Drug: Xalatan™ (Pfizer), one drop administered topically in the eye once daily for 28 days.

Clinical Investigation objectives

Primary objective: to confirm the clinical non-inferiority of the preservative-free Latanoprost eye drops compared with the marketed preservative-containing Xalatan™ (Pfizer) eye drops by the average decrease of diurnal IOP measured between the first and last visit.

Secondary objective: to compare the safety and tolerability of the product under investigation with the reference treatment.

Evaluation parameters

Efficacy evaluation: Principal efficacy endpoint was the average decrease of diurnal IOP measured between baseline and the end of the treatment.

Secondary efficacy endpoints such as best corrected log MAR visual acuity, ophtalmoscopy and ocular discomfort after intillation of the study drug were evaluated by the assessment of the differences between basal values and 7, 14 and 28 days after.

Safety evaluation: Any adverse event related or not to products to study was collected and described in the corresponding form in order to document the safety of experimental products and the tolerability to them.

Laboratory data: Biochemical parameters were determined before inclusion in the study, and at the end of the treatment phase. Any alterations was evaluated individually; clinical impact was considered and was characterized in the same way as adverse events by the investigator.

Results

The clinical non-inferiority of the preservative-free Latanoprost eye drops compared with the marketed preservative-containing Xalatan™ (Pfizer) eye drops by the average decrease of diurnal IOP was confirmed. The results were consistent for both eyes separately.

There are no differences in the number of subjects that shows ocular discomfort after instillation between those treated with Xalatan™ (Pfizer) and those treated with Latanoprost without preservatives.

The papillary excavation (ophtalmoscopy) of both eyes is not modified during the 28 days of monitoring in both groups and, therefore, the evolution of this variable in both groups is similar.

There are no modifications of the visual acuity in those subjects treated with Latanoprost without preservatives, as those treated with Xalatan™ (Pfizer).

There are no modifications of the blood pressure in those subjects that have been treated with Latanoprost without preservatives, as those that have been treated with Xalatan™ (Pfizer).

There have been no serious adverse events during the study execution.

Most of the adverse events in the subjects treated with Latanoprost without preservatives and related to the product are mild and these have been solved without any specific action.

No cause-effect relation between the observed analytical alterations and the use of the experimental products has been found.