Preservative-free fixed-dose combination of tafluprost 0.0015% / timolol 0.5% in patients with open-angle glaucoma or ocular hypertension: Clinical effectiveness, tolerability and safety in a real world setting (Taptiqom)

First published: 11/01/2018

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS22204

Study ID

36175

DARWIN EU® study

No

Study countries

- Austria
- Denmark
- Hungary
- Ireland
- Italy
- Latvia
- Netherlands
- Norway
- Russian Federation
- Spain
- Sweden
- United Kingdom

Study description

This is a prospective, non-interventional study of the efficacy, tolerability and safety of Tafluprost / Timolol in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative free eye drops.

Study status

Finalised

Research institutions and networks

Institutions

Irccs Fondazione G. B. Bietti

LKH - Universitaetsklinikum Graz austria, Rigshospitalet denmark, Bacs-Kiskun Megyei Korhaz hungary, Markusovszky Egyetemi Oktatokarhaz hungary, University of Debrecen hungary, PTE - Szemeszeti Klinika hungary, Bugat Pal Korhaz, Gyongyos hungary, Szegedi Tudomanyegyetem Szent-Gyorgyi Albert Klinikai Kozpont hungary, Szent Imre Kórház és Rendel¿intézet Szemészeti Osztály hungary, Semmelwis Egyetem SzemEszeti Klinika hungary

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Francesco Oddone

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/09/2016

Actual: 01/09/2016

Study start date
Planned: 10/04/2017

Actual: 10/04/2017

Data analysis start date
Planned: 07/10/2018

Date of final study report
Planned: 22/01/2019

Actual: 05/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANTEN

Study protocol

Taptiqom_Santen_PhIV_Protocol v2.0.pdf (2.04 MB)

Amended Protocol V5 13Feb2018_ clean_ Eng_Final (review 14feb18)_signed.pdf (1.05 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

Tolerability and safety in a real world setting

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this non-interventional study with Tafluprost / Timolol is to evaluate the effectiveness of Tafluprost / Timolol in routine clinical practice, as measured by the mean change in intraocular pressure 6 months post initiation of Tafluprost / Timolol therapy, in patients with open angle glaucoma or ocular hypertension.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, non-interventional study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TAFLUPROST

TIMOLOL

Medical condition to be studied

Glaucoma

Population studied

Short description of the study population

This study will include adults with open angle glaucoma or ocular hypertension, who received their first Tafluprost / Timolol prescription at baseline, even if Tafluprost / Timolol was not continued after the first prescription. In addition, patients must have their IOP recorded within 7 days before their first prescription of Tafluprost / Timolol, in order to be eligible for this study. Only those who provide informed consent will be included. At the time of a scheduled clinic visit, eligible patients will be invited to participate in the study and willing patients will be requested to sign an informed consent form. Once informed consent is obtained, the patient is included in the study and relevant data will be recorded during routine clinical visits.

Participation in this study is entirely voluntary; any patient may withdraw consent to participate in this study at any time. The withdrawn patient’s data will not be analysed in this study and the number of patients who withdrew consent will appear in the final study report.

Inclusion criteria

• Signed informed consent obtained before any study-related activities (study-related activities are any procedure related to extraction of data according to the protocol)

• According to the approved indications of Tafluprost / Timolol as indicated in the SPC

o Male or female patients ≥18 years of age at time of informed consent o Diagnosis of open angle glaucoma or ocular hypertension

o Insufficient IOP control with a monotherapy utilising topical beta blockers or prostaglandin analogues, necessitating the use of a combination therapy according to the judgement of the treating ophthalmologist

o Patient judged by their physician to benefit from preservative free eye drops

Exclusion criteria

• Patient pregnant or nursing

• Pregnancy planned in the following 6 months
• Presence of contraindications as listed in the SPC
• Any ophthalmologic surgery within 6 months prior to the study
• Participation in any other investigational st

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Ocular hypertension patients

Estimated number of subjects

650

Study design details

Outcomes

The primary endpoint will also be estimated as a baseline adjusted change using a normal linear regression model. In this model, change from baseline in IOP will be modelled as a function of the baseline value and relevant covariates. Mean change in intra-ocular pressure (IOP) from baseline to after 4 and 12 weeks of treatment from initiation (± 7 days)Proportion of responders at 12

weeks, defined as change from baseline IOP of 20% or moreAssessing the effectiveness of Tafluprost / Timolol in reducing clinical signs and subjective symptoms after 6 months of treatment in routine clinical practiceAssess the tolerabi

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Data analysis plan

Primary dataset/full analysis set (FAS): all patients having signed informed consent form and prescribed Tafluprost / Timolol (TT) at least once, irrespective of whether patients continued TT after first prescription.Secondary effectiveness analysis set (EAS): all patients in the FAS having continued Tafluprost/Timolol treatment for 6 months after initiation, with at least one measurement of intraocular pressure (IOP) at 6 months (± 45 days) after initiation. The primary analysis will compare IOP value at baseline and at 6 months after TT treatment start. The primary endpoint will also be estimated as a baseline adjusted change using a normal linear regression model. IOP change from baseline will be modelled as a function of the baseline value and relevant covariates. Results will be presented overall and by previous treatment and country.Secondary endpoints will be presented descriptively.

Documents

Study, other information

Glaucoma_All_site.pdf (43.95 KB)

sites final 0240-0024.pdf (47.27 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

During routine visits at 4 weeks (±7 days), 12 weeks (±7 days) and 6 months (±45 days) post first Tafluprost / Timolol prescription, site staff will enter data into the eCRF covering these visits. Only data elicited as part of standard care will be entered into the eCRF.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown