ISRCTN17779071 https://doi.org/10.1186/ISRCTN17779071

Efficacy and safety assessment of T4032 (unpreserved bimatoprost 0.01%) versus Lumigan® 0.01% in ocular hypertensive or glaucomatous patients

Submission date
05/09/2022

Recruitment status
No longer recruiting

Registration date
03/01/2023

Overall study status
Completed

Last Edited
24/09/2024

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The main study purpose is to demonstrate that T4032 works as well as Lumigan® 0.01% in terms of treating patients with ocular hypertension or glaucoma. This is an international study of 12 weeks treatment duration being performed in the US, Canada and Colombia.

Who can participate?
Patients aged 18 years old and over diagnosed with open-angle glaucoma or controlled ocular hypertension

What does the study involve?
2 study arms, 1 instillation/day in each eye involving 500 randomized patients

What are the possible benefits and risks of participating?
The possible benefits of taking part in this study may include providing relief of, or lessening of, the signs and symptoms of your health problem. Taking part in this study will help doctors to learn more about the study treatment. This may help others with similar health problems in the future.

Where is the study run from?
Laboratoires Thea (France)

3 countries are involved (US, Canada and Colombia)

When is the study starting and how long is it expected to run for?
January 2022 to March 2024

Who is funding the study?
Laboratoires Thea (France)

Who is the main contact?
Corentin Le Camus

Contact information

Type(s)
Public

Contact name
Mr Corentin LeCamus

Contact details
Laboratoires Théa
12 rue Louis Blériot
Clermont Ferrand
France
63017
+33473981436
corentin.lecamus@theapharma.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05397600

Secondary identifying numbers
LT4032-302

Study information

Scientific Title
Efficacy and safety assessment of T4032 (unpreserved bimatoprost 0.01%) versus Lumigan® 0.01% in ocular hypertensive or glaucomatous patients

Study objectives
To demonstrate the non-inferiority of T4032 compared to Lumigan® 0.01% in terms of efficacy

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/08/2022, Institutional Review Board (IRB) services (Advarra)
2. Approved 21/03/2022, WCG IRB (1019 39th Avenue, SE Suite 120 Puyallup, WA 98374, USA; +1 855 818 2289; clientservices@wcgirb.com), ref: 1-1526839-1

Study design
International multicenter randomized two-parallel-group design investigator-masked 12-week treatment duration

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Ocular hypertension and glaucoma

Interventions
Lumigan or T4032, randomised into 2 arms, investigator-masked, 12-week treatment duration, Five visits (six visits can be needed, in case of premature treatment discontinuation) and one optional visit:
Visit #1: Day-35 to Day-28 (Screening visit)
Optional Visit #1.1: to be scheduled if the investigator judges that it is necessary
Visit #2: Day 1 (Randomization visit)
Visit #3: Week 2 (Day 15±3 days)
Visit #4: Week 6 (Day 43±3 days)
Visit #5: Week 12 (Day 85±7 days)
Premature treatment discontinuation visit: in case of premature treatment discontinuation, a visit should be scheduled as soon as possible.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Bimatoprost (T4032, Lumigan)

Primary outcome measure
Intraocular pressure (IOP) in the study eye measured using tonometry at nine time-points over a 3 month-study period at 8:00 and 10:00 am and 4:00 pm at Week 2, 6, and Week 12

Secondary outcome measures

All were measured at nine time-points over a 3 month-study period at 8:00 and 10:00 am and 4: 00 pm at Week 2, 6, and Week 12

Efficacy parameters:
Efficacy assessment by the investigator

Safety parameters:
1. Ocular and systemic Adverse Event (AE) reporting
2. Assessment of the conjunctival hyperemia on McMonnies photographic scale in each eye
3. Score of each ocular sign (blepharitis, eyelid edema, iris pigmentation modification, abnormal eyelashes aspect, folliculo-papillary conjunctivitis, other ocular abnormality) in each eye using 0-3 scale
4. Corneal fluorescein staining grade according to modified Oxford grading scheme in each eye
5. Conjunctival lissamine green staining grade according to modified Oxford grading scheme in each eye
6. Tear break-up time (TBUT) in each eye
7. Far Best Corrected Visual Acuity (BCVA) in each eye
8. Ocular tolerance assessed by the investigator
9. Ocular tolerance assessed by the patient
10. Score of each ocular symptom throughout the day (irritation/burning, stinging, itching, tearing, eye dryness feeling, foreign body sensation)
11. Score of each ocular symptom upon instillation (irritation/burning, stinging, itching, tearing, eye dryness feeling, foreign body sensation)

Overall study start date
14/01/2022

Completion date
07/03/2024

Eligibility

Key inclusion criteria
1. Informed consent signed and dated. Obtained at the latest at the Screening visit (Visit #1) and prior to the initiation of any study-specific procedures

At Screening visit (Visit#1) (Day -35 to Day-28):
2. Patient aged 18 years old and over
3. Both eyes with a central corneal thickness ≥500 µm and ≤600 µm
4. Both eyes with diagnosed ocular hypertension or open-angle glaucoma (primary open-angle, pseudo-exfoliative or pigmentary glaucoma) treated and controlled for at least 6 months by any prostaglandin monotherapy. Patients with one eye with ocular hypertension and the other eye with open-angle glaucoma are eligible.
5. Both eyes with IOP ≤18 mmHg

At Randomization visit (Visit #2) (Day 1) at 8:00 am:
6. Both eyes with 22 mmHg ≤ IOP <34 mmHg and with asymmetry between eyes ≤4 mmHg
7. Patient has respected the washout period of at least 28 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Total final enrolment
688

Key exclusion criteria
1.1. History of narrow angle and/or angle closure glaucoma
1.2. Functionally significant visual field loss or progressive visual field loss during the last year and/or structural glaucoma progression during the last year detected on the OCT device routinely used by the clinical site
1.3. Advanced stage of glaucoma, defined by at least one of the following criteria:
1.3.1. Severe central visual field loss (i.e., sensitivity loss 10 dB or more in at least 2 of the 4 visual field test points closest to the point of fixation)
1.3.2. Severe visual field loss: MD <-12 dB
1.3.3. Risk of visual field worsening as a consequence of participation in the study according to the investigator's best judgement
1.3.4. Cup to disk ratio >0.8 (horizontal or vertical measurement)
1.4. History of non-responder to bimatoprost therapy

Ophthalmic exclusion criteria in at least one eye at screening and randomization visits
1.5. Far Best Corrected Visual Acuity ≥ + 0.7 Log Mar (e.g., ≤ 0.2 in decimal value or ≤ 20/100 Snellen equivalent or ≤ 50 ETDRS letters)
1.6. History of trauma, infection, clinically significant inflammation within the previous 3 months
1.7. Ongoing or known history of uveitis and/or viral infection
1.8. Ongoing ocular allergy
1.9. Clinically significant or progressive retinal disease (e.g., para/central retinal degeneration, diabetic retinopathy, retinal detachment)
1.10. Presence of at least one severe objective sign among the following:
1.10.1. Conjunctival hyperemia: Score 5 on the McMonnies scale
1.10.2. Corneal fluorescein staining (CFS) Grade 4 or 5 on the modified Oxford grading scheme
1.10.3. Severe blepharitis: Grade 3 using a 0-3 scale
1.11. Corneal ulceration
1.12. Any abnormality preventing accurate assessment e.g., reliable applanation tonometry measurement, visual field assessment, fundus examination

Systemic/non-ophthalmic exclusion criteria at screening and randomization visits
2.1. Documented uncontrolled diabetic patient
2.2. Known or suspected hypersensitivity to one of the components of the IMP (T4032 or Lumigan®) or diagnostic agents used during the study (e.g., topical anaesthetic, fluorescein, lissamine green)

2.3. History of or active relevant systemic condition incompatible with the study or likely to interfere with the study results or the patient safety according to investigator’s judgment

Specific exclusion criteria regarding childbearing potential women
3.1. Pregnancy or breast-feeding
3.2. Childbearing potential woman neither surgically sterilized nor using an adequate contraception, as oral contraceptive, intra-uterine device, subcutaneous contraceptive implant, vaginal ring, patch

Exclusion criteria related to general conditions at screening and randomization visits
4.1. Alcohol addiction and/or heavy smoker, according to the investigator’s judgement
4.2. Inability of patient to understand the study procedures or to give informed consent
4.3. Non-compliant patient (e.g., non-compliance to the IMP, not willing to attend a visit or complete a self-questionnaire, way of life interfering with compliance)
4.4. Participation in this study at the same time as another clinical study
4.5. Participation in this study within the 4 weeks after the end of a previous clinical study (or within 5 half-lives of the previously tested product if longer than 4 weeks)
4.6. Patients previously randomized in this study
4.7. Patient being institutionalized because of legal or regulatory order, inmate of psychiatric wards, prison or state institutions, or employee of the study sites or of the Sponsor’s company

Exclusion criteria related to previous and concomitant treatments (medications/non-medicinal therapies/procedures)
5.1. Patient with previous, current or anticipated prohibited treatment (or prohibited modification of treatment regimen)

Date of first enrolment
22/06/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
Canada

Colombia

United States of America

Study participating centre
Scheie Eye Institute (Eydie Miller-Ellis)
51 North 39th Street
Philadelphia
United States of America
19104

Study participating centre
Prism Eye Institute (Irfan Nizarali Kherani)
2201 Bristol Circle Suite 100
Oakville
Canada
L6H0J8

Study participating centre
Clinique d'ophtalmologie Bellevue (Dr. Paul Harasymowycz)
4135 rue de Rouen
Montral
Canada
H1V1G5

Sponsor information

Organisation
Laboratoires Thea

Sponsor details
Laboratoires Théa
12 rue Louis Blériot
Clermont Ferrand
France
63017
+33 680382020
corentin.lecamus@theapharma.com

Sponsor type
Industry

Website
https://www.laboratoires-thea.com

Funder(s)

Funder type
Industry

Funder Name
Laboratoires Thea

Results and Publications

Publication and dissemination plan

Intention to publish date
30/10/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date