

Comparison performance of preserved versus unpreserved Levocabastin eyedrops in allergen challenge

Submission date 26/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/09/2011	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
523

Study information

Scientific Title

A Colateral, Double-Masked, Randomized Study to Evaluate Preservative-Free Levocabastine 0.05% Ophthalmic Solution When Compared to Preserved Levocabastin 0.05% Ophthalmic Suspension or Preservative-Free Levocabastine Ophthalmic Solution Vehicle During Allergen Challenge

Acronym

Levocabastine

Study objectives

Evaluation of efficacy and safety of Prerservative-free Levocabastine ophthalmic solution compared to Preserved Levocabastine ophthalmic suspension and Preservative-free Levocabastine ophthalmic solution vehicle in prevention of allergic conjunctivitis induced by ocular allergen challenge

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local ethics committee (Comité de Protection des Personnes CPP Ile de France III) on the 31st of July 2007 (Ref: CPP Dossier No 2445)

Study design

Single centre contralateral double blind randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Allergic Conjunctivitis

Interventions

1. Preservative-free Levocabastine 0.05% ophthalmic solution (formula LCM-1218)
2. Preserved Levocabastine 0.05% ophthalmic suspension (Levophta, formula LCM-1215)
3. Preservative-free Levocabastine ophthalmic solution vehicle (formula LCM-1228)

3/4 of patients will receive (1) in one eye and (2) in the second eye
1/4 of patients will receive (3) in one eye and (2) in the second eye

One drop of the applicable medication/placebo will be administered by study personnel at 10 min (Visit 3) or 4 hours (Visit 4) prior to CPT.
No further follow up.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Sum score for conjunctival hyperaemia (Grade 0-3) and itching (Grade 0-4) at 3, 5, and 10 minutes after CPT at Visits 3 and 4

Secondary outcome measures

1. Individual scores for the following, at 3, 5, and 10 minutes after CPT at Visit 3 and 4
 - 1.1. conjunctival hyperaemia
 - 1.2. itching
 - 1.3. eyelid swelling
 - 1.4. conjunctival chemosis
 - 1.5. tearing
2. Proportion of eyes with a late phase reaction within 24 hours after CPT at Visit 3 and 4
3. Safety Endpoints:
4. Visual acuity (Monoyer scale)
5. Slit lamp
6. IOP
7. Subjective tolerance upon treatment administration
8. Adverse events

Overall study start date

29/10/2007

Completion date

25/03/2008

Eligibility

Key inclusion criteria

1. Healthy
2. Volunteers
3. Male or female
4. 18-50 years old
5. History of allergic conjunctivitis
6. Normal screening ocular examination
7. Best corrected distance visual acuity (VA) must be 8/10 (Monoyer scale) or more
8. Intraocular pressure (IOP) must be <21 mm Hg
9. Positive screening conjunctival provocation test (CPT) including at least moderate itching and

hyperaemia

10. Women of childbearing potential must have a negative pregnancy test

11. Contact lens wearers must agree to not wear contact lenses when CPTs are conducted

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Both

Target number of participants

92

Key exclusion criteria

1. Any ocular or systemic disease
2. Known hypersensitivity to the study drugs or their components
3. Allergic conjunctivitis due to an allergen other than grass pollen
4. Subjects who don't have discontinued use of certain medications up to 6 weeks prior to study entry
5. Subjects who have previously undergone hyposensitization therapy for grass pollen within 3 months prior to study entry
6. Subjects who have previously undergone ocular laser treatment or ocular surgery within 6 months prior to study entry

Date of first enrolment

29/10/2007

Date of final enrolment

25/03/2008

Locations

Countries of recruitment

France

Study participating centre

SGS Aster,

Paris

France

75015

Sponsor information

Organisation

Laboratoire Chauvin, Bausch & Lomb Inc. (France)

Sponsor details

416, rue Samuel Morse
Montpellier Cedex 2
France
34961

Sponsor type

Industry

ROR

<https://ror.org/018qejt38>

Funder(s)

Funder type

Industry

Funder Name

Laboratoire Chauvin, Bausch & Lomb Inc. (France)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration