# Comparison performance of preserved versus unpreserved Levocabastin eyedrops in allergen challenge

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

### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Didier Chassard

#### Contact details

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## Additional identifiers

Protocol serial number 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

#### Study type(s)

Prevention

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

50 years

#### Sex

All

#### 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)

#### **ROR**

https://ror.org/018qejt38

# Funder(s)

#### Funder type

Industry

#### Funder Name

Laboratoire Chauvin, Bausch & Lomb Inc. (France)

# **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 Participant information sheet 11/11/2025 No Yes