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Comparison performance of preserved versus unpreserved Levocabastin eyedrops in allergen challenge

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)

Primary study design
Interventional

Study design
Single centre contralateral double blind randomised controlled trial

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