ISRCTN31673586 https://doi.org/10.1186/ISRCTN31673586

Comparing the after-use sensation and safety of long acting (LA) carteolol 2 % versus timolol LA 0.5 % in simple intra-ocular hypertension and glaucoma

Submission date 03/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/03/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/03/2010	**Condition category** Eye Diseases	[_] Individual participant data [_] 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

Protocol serial number
#529

Study information

Scientific Title
Randomised, parallel-group, multicentre study to evaluate the after-use sensation and safety of carteolol LA 2% versus timolol LA 0.5% in simple intra-ocular hypertension and glaucoma

Acronym
Carteolol

Study objectives
In this study the hypothesis will be tested that a 3-month treatment with Carteolol is superior to a 3-month treatment with Timolol in the subjective tolerance (ocular discomfort) upon instillation.
Ocular hypertension or Primary Open Angle Glaucoma (POAG) (superiority design)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Belgium (Lead Centre): Ethics Committee of UZ Leuven (KUL) approved on the 10th of April 2008 (ref: ML 4750)
2. Czech Republic: Local ethics committee (Eticke Komise) approved on the 17th of January 2008 (refs: protocol UtCIV; approval no. 1743107S-MEK)
3. France: Local ethics committee (Comité de protection des personnes Sud Est 6) approved on the 2nd of November 2007 (ref: AU 714)
4. Poland: Local ethics committee (Komisja Bioethyczna) approved on the 6th of January 2007 (ref: KB-517/2007)
5. Portugal: National Ethics Committee for Clinical Investigation (CEIC) approved on the 19th of May 2008 (ref: 0804AU135)

Study design
Investigator-masked parallel group randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unilateral or bilateral ocular hypertension; Primary Open Angle Glaucoma (POAG)

Interventions
Written informed consent was obtained at baseline visit 1 (day 0). Eligibility was determined by reviewing medical history, recording of concomitant medication, external eye examination (signs of inflammation on eye lids, lid closure, lid motility, bulbar motility, conjunctival injection), and a check of inclusion and exclusion criteria.
Eligible patients were randomised to receive either
1. Carteolol LA 2%: Daily, 1 drop at 8 AM in the eye(s) to be treated over 3 months
2. Timolol LA 0.5%: Daily, 1 drop at 8 AM in the eye(s) to be treated over 3 months
Patients received the appropriate medication and diary card.

Follow up visits were carried out on days 30 and 90 (± 3 days). Further medication and diary cards were distributed on day 30 only. Used and unused bottles and diary cards were collected at both visits. Patients were not followed up beyond the end of the intervention period.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Evaluation of the subjective tolerance upon instillation (rate of patients experiencing symptoms of discomfort), graded as very good, good, bad or very bad, measured at baseline, 1 and 3 months

Key secondary outcome(s))
1. Assessment of each of the symptoms of the Glaucoma Symptom
Scale [15] (Yes/ No): burning/smarting/stinging, tearing, dryness, itching, soreness/tiredness, feeling of something in the eye, blurry/dim vision, hard to see in daylight, hard to see in dark places and halos around the light (for those who report a given symptom, a bothersome scale will be used: very, somewhat, a little, not at all)
2. Slit lamp examination (examination of conjunctiva, cornea, iris, lens, anterior chamber), performed at baseline, 1 and 3 months
3. Tear-film-break-up-time-test (BUT-test; sec), performed at baseline, 1 and 3 months
4. Fluorescein staining of the cornea, performed at baseline, 1 and 3 months
5. Van Bijsterveld test (Lissamine green), performed at baseline, 1 and 3 months
6. IOP measured at 12 PM (+/- 30mn), measured at baseline, 1 and 3 months
7. Assessment of Visual acuity and visual field, measured at baseline (if no visual field performed during the previous 3 months) and at 3 months
8. Fundoscopy, performed at baseline, 1 and 3 months
9. Adverse events, reported at 1 and 3 months
10. Compliance, reported at 1 and 3 months

Completion date
10/08/2009

Eligibility

Key inclusion criteria
1. Adult patients, men or women
2. Suffering from unilateral or bilateral ocular hypertension or POAG
3. Intraocular Pressure (IOP) controlled with beta-blocker monotherapy (IOP < 21mmHg and visual field stable)
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age < 18 years
2. IOP not controlled with beta-blocker monotherapy
3. Angle closure, congenital and secondary glaucoma
4. Any pathology contraindicating an IOP measurement
5. Any intraocular infection or inflammation, ocular trauma, ocular surgery or laser trabeculoplasty within the previous 3 months
6. Previous intolerance to carteolol or timolol, or to any other ingredients of the tested products
7. Beta-blocker contraindications
8. Ocular corticosteroids
9. Contact lens wearers
10. Severe systemic or ocular disease
11. Hypotension
12. Drug, alcohol abuse
13. Involvement in the last 30 days in any other investigational drug study
14. Expected change in treatment of concomitant disease
15. Patients with a history of recurrent ocular herpes and/or recurrent uveitis
16. Change in ocular treatment within the last month
17. Patients treated with other topical ocular treatment within the last month
18. Pregnant or lactating women
19. Women of child-bearing potential considering becoming pregnant during the course of the study and those not taking precautions to avoid pregnancy
20. Patients for whom, in the physician's opinion, any of the protocol procedures may pose a special risk not outweighed by the potential benefits of participating in the study
21. Patients who are unlikely to comply with the study protocol or who are likely to be moving and lost to follow up in the study period
22. Patients with neurotic, psychiatric disorders or suicidal tendencies

Date of first enrolment
11/12/2007

Date of final enrolment
10/08/2009

Locations

Countries of recruitment
Belgium

Czech Republic

France

Poland

Portugal

Study participating centre
CHU de Clermont Ferrand Service
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Sponsor information

Organisation
Dr. Mann Pharma GmbH, Bausch & Lomb Inc. (Germany)

ROR
https://ror.org/049ncrn81

Funder(s)

Funder type
Industry

Funder Name
Bausch & Lomb GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration