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Efficacy and safety of Hydrocortison-POS N1% and 2.5% versus Ficortril 0.5% in the treatment of acute inflammation of the ocular surface or adnexa for which steroid treatment is indicated

Submission date
02/09/2013

Recruitment status
No longer recruiting

Registration date
18/09/2013

Overall study status
Completed

Last Edited
03/06/2014

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Eye ointments containing hydrocortisone acetate have been used for years to treat inflammation of the eye such as conjunctivitis, keratitis or inflammation of the eye lid margin. Hydrocortisone acetate is available in eye ointments of different strength (0.5%, 1% and 2.5%). The aim of the study was to confirm the effectiveness and safety of eye ointments containing hydrocortisone actetate and to show whether the different strengths cause different clinical results.

Who can participate?
Male and female patients between 18 and 75 years old suffering from non-infectious inflammation of the eye and/or eye lid such as allergic conjunctivitis or acute allergic reaction of the eye lid with inflammation and swelling which should be treated with corticoid-containing eye care products like hydrocortisone acetate eye ointment.

What does the study involve?
Patients were randomly allocated to receive one of the three treatments:
Group 1 Hydrocortisone acetate 0.5 % (Ficortril® 0.5%)
Group 2: Hydrocortisone acetate 1 % (Hydrocortison-POS® N 1 %)
Group 3 : Hydrocortisone acetate 2.5 % (Hydrocortison-POS® N 2.5 %)
The eye specialist did their standard eye examination and assessed the severity of signs and symptoms and the patients assessed the tolerance of the eye ointments.

What are the possible benefits and risks of participating?
The results show that Hydrocortison-POS® N 1 % and 2.5 % are efficacious and safe treatments of acute inflammations of the outer eye. They showed significantly better efficacy than the control group treated with Ficortril® 0.5%. All trial medications were safe and well tolerated according to the patients and doctors reports.

Where is the study run from?
10 different eye hospitals in Ukraine.

When is the study starting and how long is it expected to run for?
The study started in May 2009 and completed in March 2011.

Who is funding the study?
URSAPHARM Arzneimittel GmbH (Germany).

Who is the main contact?
Prof Pavel A. Bezdetko

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2007-005507-18

Protocol serial number
HYDROPH2

Study information

Scientific Title
Efficacy and safety of Hydrocortison-POS N 1% and 2.5% versus Ficortril 0.5% in the treatment of acute inflammation of the ocular surface or adnexa for which steroid treatment is indicated - a multi-centre, randomised, double-blind, parallel-group, phase III comparison

Study objectives
1. To show superiority of Hydrocortison-POS N 1% and 2.5% versus Ficortril 0.5% regarding the time to 50% reduction in sum score of signs and symptoms.
2. To show superiority of Hydrocortison-POS N 2.5% versus Hydrocortison-POS N 1% regarding the time to 50% reduction in sum score of signs and symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)
The Central Ethics Committee, Narodnogo opolchennya Str. 5, 03680 Kyiv, Ukraine, 10/04/2009

Study design
Multi-centre randomised double-blind three-arm parallel group study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-infectious disease of the eye and ocular adnexa, i.e., seasonal or perennial allergic conjunctivitis, acute allergic blepharitis or blepharoconjunctivitis, or allergic lid oedema, with acute inflammation of the ocular surface or adnexa

Interventions
Patients were randomly allocated to one of three study arms:

Arm 1: Hydrocortisone acetate 0.5 % (Ficortril® 0.5%) (n=133 patients)
Arm 2: Hydrocortisone acetate 1 % (Hydrocortison-POS® N 1%) (n= 140 patients)
Arm 3: Hydrocortisone acetate 2.5 % (Hydrocortison-POS® N 2.5%) (n=138 patients)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
1. Hydrocortison-POS N 1 % and 2.5 % 2. Ficortril 0.5 %

Primary outcome(s)
The primary and secondary outcomes were measured by standard ophthalmological methods. The ophthalmologist assessed clinical signs and symptom by score values during a slit lamp examination. Additionally visus and intraocular pressure were measured. Patient was also asked to assess the local tolerance by a questionnaire.

Ophthalmological slit lamp examination:
Time to first occurrence of at least 50% in sum score of signs and symptoms

Key secondary outcome(s))
Efficacy
The three treatment groups were compared pair-wise with regard to the differences in subscores of objective and subjective signs and symptoms between end of treatment and baseline, as well as the differences in time to 50% reduction of objective signs and subjective symptoms, responders and remitters, differences in the scores of single items of the CSS, treatment duration, and global assessments of efficacy.

Safety
To assess the different outcomes of the three treatments on intra-ocular pressure (IOP), to evaluate tolerability by (relative) frequency of (serious) adverse events, abnormalities of vital signs, visual acuity test and fluorescein corneal staining in the three treatment groups, and to compare global assessment of tolerability between each pair of the three treatment groups

1. Sum score of subjective and objective signs
2. Sum score of objective signs
3. Sum score of subjective symptoms
4. Time to first occurrence of at least 50% reduction in sum score for objective signs
5. Time to first occurrence of at least 50% reduction in sum score for subjective signs
6. Responder (CSS improvement by ≥ 50%) and remitter (CSS=0) rates
7. Treatment duration until CSS=0
8. Global rating of efficacy
9. Intra-ocular pressure
10. Visual acuity
11. Vital signs
12. Fluorescein corneal staining
13. Adverse events
14. Global rating of tolerability

Measurements were done at baseline and on day 2, 4, 7, 10, (and if required) 14.

Completion date
14/03/2011

Eligibility

Key inclusion criteria
1. Female or male outpatients aged 18 to 75 years old (inclusive) with a non-infectious disease of the eye and ocular adnexa, i.e., seasonal or perennial allergic conjunctivitis, acute allergic blepharitis or blepharoconjunctivitis, or allergic lid oedema, with acute inflammation of the ocular surface or adnexa for which topical steroid treatment is advisable
2. A clinical sum score of signs and symptoms of at least 10 with at least one item scored as 2 (moderate) or 3 (severe) at baseline.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Incapability of understanding the language in which the written patient information is given
2. Presence or history of drug or alcohol abuse
3. Presence of any malignancy during the past 5 years
4. The patient is a woman of childbearing potential who does not use a reliable method of contraception
5. The patient is a pregnant or breast feeding woman
6. Participation in a concurrent clinical trial or in another trial within the past 4 weeks
7. Previous participation in this trial or the patient is the investigator him/herself
8. Pre-treatment which is not permitted
9. Concomitant treatment which is not permitted
10. Allergy or hypersensitivity to any ingredients of the trial medication
11. Any contraindication for the use of steroids: e.g. bacterial, some specific viral or fungal eye infections, glaucoma [except open-angle glaucoma with controlled Intraocular pressure (IOP)], cataract (except early-stage cataract), etc.
12. Findings with fluorescein corneal staining at baseline which prohibit steroid treatment
13. Eye discharge (yellowish) with score of 1 or above at baseline as assessed by the investigator
14. Ocular injury and/or ocular surgery within 3 months prior to trial participation (preceding intra ocular laser surgery expressively permitted)
15. Systemic or topical steroids within 1 month prior or during trial participation
16. Contact lenses
17. Changes in eye hygiene measures after study inclusion
18. Any systemic disease which prohibits steroid treatment, e.g. severe osteoporosis, unstable diabetes mellitus, Cushing syndrome, etc.

Date of first enrolment
20/05/2009

Date of final enrolment
14/03/2011

Locations

Countries of recruitment
Ukraine

Study participating centre
Head of Department of Ophthalmology
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Sponsor information

Organisation

URSAPHARM Arzneimittel GmbH (Germany)

ROR
https://ror.org/031t42b47

Funder(s)

Funder type
Industry

Funder Name
URSAPHARM Arzneimittel GmbH (Germany)

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?
Results article	results	10/05/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes