

# 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

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>02/09/2013   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>18/09/2013 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>03/06/2014       | <b>Condition category</b><br>Eye Diseases         | <input type="checkbox"/> 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 acetate 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

**Contact name**  
Prof Pavel A. Bezdetko

**Contact details**  
Head of Department of Ophthalmology  
Kharkov District Clinical Hospital  
Pr. Lenina 4  
Kharkov  
Ukraine  
61002

## 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  $\geq 50\%$ ) 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**

Kharkov

Ukraine

61002

## **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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 10/05/2014   |            | Yes            | No              |