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A one month study of the efficacy and safety of SVS20 versus carbomer and saline in patients with bilateral moderate dry eye syndrome: a randomised, double blind, controlled, parallel group, pilot, phase II study

Submission date
05/02/2008

Recruitment status
No longer recruiting

Registration date
13/02/2008

Overall study status
Completed

Last Edited
13/02/2008

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
SVS20-HUN-05-01

Study information

Scientific Title

Study objectives
To assess the efficacy and safety of SVS20 versus saline (as a basic standard reference product) and carbomer (as a standard treatment with a marketing authorisation in most EU countries) in patients with bilateral moderate dry eye syndrome due to Sjogren's syndrome (immune exocrinopathy) or diagnosed as a primary syndrome.

Please note that the results of this study were used to calculate the sample size of a more recent phase III multicentre study conducted in France and UK. For more details on this phase III study, please visit the ISRCTN record at http://www.controlled-trials.com/ISRCTN91412460.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. The National Ethics Committee for Clinical Pharmacology (KFEB) on the 29th June 2005
2. The Ministry of Health on the 14th July 2005

Thereafter, local Institutional Review Board (IRB) at each centre gave favourable opinions on 13 September 2005 (Dr. Deák), 5 October 2005 (Dr. Sohajda), 18 October 2005 (Dr. Márta), 21 November 2005 (Dr. Zeher) and 2 December 2005 (Dr. Bereczki).

Study design
Randomised, double blind, controlled, parallel group, pilot, phase II study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dry eye syndrome

Interventions
There were three arms:
1. SVS20
2. Saline
3. Carbomer

Patients instilled 2 - 4 times a day one of these eye drops. Treatment duration was 1 month with a previous period of wash-out of 112 to 16 days.

The following parameters were measured at V1 (day 16 to day 12), V2 (day 0) and V3 (day 28):
1. BUT
2. Schirmer I test
3. Lissamine and fluorescein staining
4. BCVA

5. Slit lamp examination
6. Symptoms intensity and frequency

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
SVS20, carbomer

Primary outcome(s)
Since this study was a phase II there were no primary or secondary outcomes. Our aim was to analyse the efficacy and safety of SVS20 versus saline and carbomer and to find a parameter that could be used as the primary criterion for the following pivotal phase III study (ISRCTN91412460). Therefore, the following parameters were assessed:
1. Efficacy and tolerability:
1.1. Number of instillations
1.2. Staining with lissamine green
1.3. Symptom intensity and frequency
1.4. Repercussion of symptoms on activities of daily life
1.5. Comfort of the eye drops (presence and duration of blurred vision after instillation)
1.6. Slit lamp examination
1.7. Tear volume (Schirmer I test)
1.8. Tear film BUT
1.9. Corneal staining with fluorescein
1.10. Global evaluation of efficacy

2. Safety:
2.1. Comfort of the eye drops (presence and duration of blurred vision)
2.2. BCVA
2.3. Impairment of dry eye symptoms
2.4. Ocular adnexa examination
2.5. Adverse events reporting

Parameters were measured at V1 (Day-16 to Day-12), V2 (Day 0) and V3 (Day 28).

Key secondary outcome(s))
No secondary outcome measures

Completion date
21/06/2006

Eligibility

Key inclusion criteria
1. Signed informed consent
2. Male and female patients aged 18 years and over
3. Patients with at least a three-month documented history of bilateral moderate dry eye due to Sjogren's syndrome (immune exocrinopathy) or diagnosed as a primary syndrome

4. Patients with total score of staining with lissamine green of at least 5/12 and not more than 10 /12 for each eye
5. Patients with at least two symptoms of dry eye among soreness, scratchiness, dryness, grittiness and burning each:
5.1. Occurring at least often and
5.2. Rated at least 30 mm and not more than 70 mm on the 0 to 100 mm visual analogue scale (VAS)
6. Patients with at least two out of three following objective parameters:
6.1. Schirmer test less than or equal to 10 mm wetting/5 minutes for each eye
6.2. Tear film break-up time (BUT) less than or equal to 10 seconds for each eye
6.3. Staining with fluorescein with a total score greater than or equal to 3/7 for each eye
7. Eligible patients using the following medications should have been taking them continuously for the two months before the screening visit and the dose should not have changed during the whole trial:
7.1. Tricyclic antidepressive agents
7.2. Anti-histaminic agents
7.3. Phenothiazines
7.4. Cholinergic agents
7.5. Antimuscarinic agents
7.6. Non-steroidal anti-inflammatory drugs (NSAIDs)
7.7. Beta-blockers
7.8. Immunomodulators
7.9. Anti-acneic agents
7.10. Diuretic agents
8. Female patients should be post-menopausal or be using a recognised, reliable method of contraception for at least three months before selection
9. Patients complying with the local regulations (e.g. social security system)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who respond to Unilarm® during or at the end of the run-in period so that their inclusion criteria are not met at D0 examinations
2. Patients with unilateral dry eye
3. Severe dry eye syndrome, defined as:
3.1. Staining with fluorescein with a depth score less than 3 in any eye and/or
3.2. Severe bulbar conjunctival hyperaemia (score of 4) in any eye and/or
3.3. Severe limbal hyperaemia (score of 4) in any eye and/or

3.4. Severe palpebral observation (score of 4) in any eye and/or
3.5. Severe blepharitis in any eye
4. Patients who underwent:
4.1. Refractive surgery within the last 12 months before selection and/or
4.2. Any other ocular surgery or ocular trauma within the last four months before selection
5. Patients taking the following systemic concomitant medications within the last two months before selection:
5.1. Corticosteroids and/or
5.2. Tetracyclines
6. Patients requiring concomitant in-eye medication for the whole trial, except Unilarm® during the selection period only
7. Patients with abnormality of the nasolacrimal drainage apparatus
8. Patient with permanent occlusion of lacrimal puncta in any eye
9. Patient with temporary punctal plug within two months before selection in any eye
10. Patients with other diseases or characteristics judged by the investigator to be incompatible with the frequent assessments needed in this study or with reliable instillation of the products (for example disability of the upper limbs)
11. Patients who participated in any other clinical trial within the last 30 days before selection
12. Patients with known hypersensitivity to hyaluronic acid or any component or procedure used in the study
13. Patients who need or intend to wear contact lens during the whole trial
14. Patients with best corrected visual acuity (BCVA) less than 1/10 in any eye
15. Pregnant or lactating females
16. Known human immunodeficiency virus (HIV) positive patients, if they belong to an anamnestic known risk group like drug addicts, etc., or if there is any reasonable doubt about HIV a validated test must be performed
17. Patients with a concomitant diagnosis of sarcoidosis, non-hodgkin lymphoma, bone marrow transplant or any secondary Sjogren's syndrome due to rheumatoid diseases or as an adverse event possibly of any other prior of concomitant medication

Date of first enrolment
10/11/2005

Date of final enrolment
21/06/2006

Locations

Countries of recruitment
Hungary

Study participating centre
Szent János Kórház
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Sponsor information

Organisation
TRB Chemedica International SA (Switzerland)

ROR
https://ror.org/012pz6314

Funder(s)

Funder type
Industry

Funder Name
TRB Chemedica International SA (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration