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A 3-month study of the efficacy and safety of SVS20 in patients with bilateral moderate dry eye syndrome: A prospective, double-masked, randomised, controlled, parallel-group, 3 arm, multicentre, phase III trial.

Submission date 01/06/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/06/2007	**Overall study status** Completed	
Last Edited 02/05/2014	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SVS20-EUR-06-01

Study information

Scientific Title

Study objectives
The aim of this study is to assess the efficacy and safety of SVS20 vs saline and carbomer in patients with bilateral moderate dry eye syndrome due to Sjögrens syndrome (immune exocrinopathy) or diagnosed as a primary syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. France: CPP 8 Ile de France on the 09/07/2007 (ref: 07 06 39). Amendments performed on 28 /09/2007 and 12/03/2008.
2. France: AFFSAPS (MoH) on the 23/08/2007 (ref: A70459-55). Amendments performed on 18/04 /2008.
3. UK: South East Research Ethics Committee on the 12/09/2007 (ref: 07/H1102/86). Amendments performed on 18/10/2007 and 03/04/2008.
4. UK: MHRA on the 24/07/2007 (ref: 31838/0001/001-0001 and -0002). Amendments performed on 22/04/2008.

Study design
Prospective, double-masked, randomised, controlled, parallel-group, 3 arm, multicentre, phase III trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Bilateral moderate dry eye syndrome / ophthalmology

Interventions

Patients will be asked to instill SVS20 (an eyedrop; active ingredient: Sodium Hyaluronate [SH]) or saline plus carbomer 2-4 times per day of for 3 months.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Symptom frequency at baseline, 1 month, 2 and 3 months.

Secondary outcome measures
The following will be assessed at baseline, 1 month, 2 and 3 months:
1. General ophthalmic examinations
2. Break-Up Time (BUT) of the tear film
3. Tear production assessed by the Schirmer test
4. Clinical state of the ocular surface assessed by fluorescein and lissamine staining
5. Symptom intensity
6. Presence and duration of blurred vision upon instillation and global evaluation

Overall study start date
15/10/2007

Completion date
28/02/2009

Eligibility

Key inclusion criteria
1. Signed informed consent
2. Male and female patients aged 18 years and over
3. With at least a 3-month documented history of moderate dry eye due to Sjögrens syndrome or diagnosed as a primary syndrome before the selection visit
4. With at least 2 symptoms of dry eye among soreness, scratchiness, dryness, grittiness and burning each:
4.1. At least occurring often and
4.2. Rated at least 30 mm and not more than 70 mm on the 0 to 100 mm Visual Analogue Scale (VAS)
5. Moderate dry eye defined as at least 3 out of the 4 following objective parameters:
5.1. Reduced tear volume: Schirmer test ≤ 10 mm wetting/5 min for each eye
5.2. Tear film instability: Break-Up Time (BUT) ≤ 10 seconds for each eye
5.3. 3/7 for each staining with fluorescein with a total score (type + extent) of eye
5.4. Patient with total score (nasal + corneal conjunctiva + temporal conjunctiva) of staining with lissamine green of at least 3/12 for each eye
6. If the patient takes the following medications that influence tear production, he/she should have taken these products continuously for 2 months before the selection visit and dose will not change during the whole trial:
6.1. Tricyclic antidepressive agents
6.2. Anti-histaminic agents

6.3. Phenothiazines
6.4. Cholinergic agents
6.5. Anti-muscarinic agents
6.6. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
6.7. Beta-blockers
6.9. Immunomodulators
6.10. Anti-acneic agents and
6. 11. Diuretic agents
7. Female patients should be post-menopausal or be using recognised, reliable methods of contraception for at last 3 months before the selection visit

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Patients with unilateral dry eye
2. Severe dry eye syndrome, defined as:
2.1. Staining with fluorescein with a depth score greater or equal to 3 and / or
2.2. Severe bulbar conjunctival hyperaemia (score of 4) and / or
2.3. Severe limbal hyperaemia (score of 4) and / or
2.4. Severe palpebral observation (score of 4) and / or
2.5. Severe anterior or posterior blepharitis
2.6. Patients who underwent: refractive surgery within the last 12 months before selection and /or any other ocular surgery or ocular trauma within the last 4 months before selection
3. Patients taking the following systemic concomitant medications within 2 months before selection and for the whole trial:
3.1. Corticosteroids and/or
3.2. Tetracyclines
4. Patients taking cyclosporine within the 4 weeks prior to screening (between 16 to 7 days prior to intervention) through the duration of the treatment period
5. Patients requiring concomitant in-eye medication for the whole trial, except Unilarm® during the selection period only
6. Abnormality of the nasolacrimal drainage apparatus
7. Patient with permanent occlusion of lacrimal puncta in any eye
8. Use of temporary punctal plug within 2 months before the selection visit in any eye
9. 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)
10. Known hypersensitivity to hyaluronic acid or any component or procedure used in the study

11. Patients who participated in any other clinical trial within the last 30 days before selection
12. Patients who need or intend to wear contact lens during the whole trial
13. Patients with Best-Corrected Visual Acuity (BCVA) < 1/10 in any eye
14. Pregnant or lactating females

Date of first enrolment
15/10/2007

Date of final enrolment
28/02/2009

Locations

Countries of recruitment
France

United Kingdom

Study participating centre
Service dOphtalmologie
Paris
France
75012

Sponsor information

Organisation
TRB Chemedica International SA (Switzerland)

Sponsor details
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1211

Sponsor type
Industry

Website
http://www.trbchemedica.com/

ROR
https://ror.org/012pz6314

Funder(s)

Funder type
Industry

Funder Name
TRB Chemedica International SA (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/06/2012		Yes	No