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Performance of [Eyes]™ cream after eyelid surgery

Submission date 25/02/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 25/03/2010	**Overall study status** Completed	
Last Edited 25/03/2010	**Condition category** Surgery	

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
538

Study information

Scientific Title

Randomised, parallel, open study of the in vivo performance of [Eyes]™ restructuring and regenerating cream in the follow-up care after standard post surgery care in uncomplicated eyelid surgery

Acronym
EYES

Study objectives
Evaluation of the effect of the restructuring and regenerating cream of the brand [Eyes]™ applied following the standard care and after removal of the stitches and complete wound closure in uncomplicated eyelid surgery, on skin colour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Comité de Protection des Personnes Ile de France VIII; Hôpital Ambroise Paré-9) on the 23rd of November 2007 (ref: 07 10 61)

Study design
Single centre open label randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Condition of skin (colour and elasticity) after eyelid surgery

Interventions
After standard post surgery care (removal of stitches), the upper eyelid will be cleaned with an eye-wash-solution (Ophtaxia) - all patients.
One group will then apply the investigational product, [Eyes]™ on the upper eyelid twice a day for 29 days.
The other group will get no treatment.
Both groups will have "Codexial Vaseline stérilisée" available to treat any discomfort

Intervention Type
Procedure/Surgery

Phase

Phase IV

Primary outcome measure
Colour of the skin around the scar through chromametry at day 1, day 15, day 22, and day 29

Secondary outcome measures
Main secondary criterion:
1 Elasticity of the skin around the scar with a Cutometer at day 1, 15, 22 and 29
Further sec. criteria:
2. Assessment of the peri-cicatrical skin colour, the surface of the scar and the suppleness of the peri-cicatricail area at day 1, 15, 22 and 29
3. Photograph of the scar for image analysis of its surface at day 1, 15, 22 and 29
4. Photograph of the scar and the eyelid for image analysis of the oedema at day 1, 15, 22 and 29 self-assessment of the peri-cicatricial skin colour, the surface of the scar and the suppleness of the peri-cicatricial area at day 1, 15, 22 and 29
5. Questionnaire about the skin state at day 15, 22 and 29
6. Questionnaire about the investigational product at day 15, 22 and 29 - only for patients receiving the product
7. Dermatological and ophthalmological tolerance follow-up at day 15, 22 and 29

Overall study start date
01/01/2008

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Voluntary
2. Caucasian
3. Male or female
4. 18-65 years old
5. Representing all natures of skin
6. Uncomplicated eyelid surgery (excluding canthus): ptosis, aesthetic blepharoplasty, functional blepharoplasty, benign tumour of the upper eyelid or other benign problem with a scar having the length of the ptosis type
7. Followed immediate standard post surgery care: saline solution for cleaning, antiseptic drop, Vitamin A ointment
8. Stitches have been removed more than 24 hours and less than 72 hours previously (stitches removed approx. 7 days after surgery)
9. Not tanned
10. Willing to commit to no sun or artificial U.V. exposure during the entire study period
11. Not using self-tanning lotions on the face
12. Agree to come to the clinical unit with no make-up at all
13. Agree to wash their face with water only when coming to the clinical unit
14. Able to give their written participation consent
15. Affiliated to the social security in accordance to the recommendations of the French law about biomedical research

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Scar is not satisfactory
2. History of trauma in study eye
3. History of skin disease inducing a cicatrisation delay
4. Traumatic and complicated eyelid surgery
5. Any progressive pathology requiring the use of topical or systemic anti-inflammatory or anti-infectious agents
6. Insulin dependent diabetes
7. History of intolerance to the investigational product
8. Monocular patients
9. Patients treated with local or systemic anti-inflammatory drugs within 10 days prior to surgery
10. In case of surgery on the second eye, the patient is to be excluded if he was already included for the first study eye
11. Taking part of another study during the study period
12. Cannot commit to the absence of pregnancy and breastfeeding during the study period
13. Significant medical history, including history of medical or psychiatric illness or major surgery, suffering from acute or chronic or progressive illnesses, or presenting a dermatological or ophthalmological pathology likely to interfere with the data of the study
14. Being deprived of his/her freedom
15. Period of exclusion in the national file (VRB: Voluntaires pour la recherche biomédicale)
16. Unwilling to give their written informed consent
17. Not contactable by phone in case of emergency
18. PERITESCO's staff members (Note: PERITESCO is the conducting CRO for this study)
19. Does not fulfil the inclusion criteria

Date of first enrolment
01/01/2008

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
France

Study participating centre
Péritesco,
Paris
France
75001

Sponsor information

Organisation
Laboratoire Chauvin, Bausch & Lomb Inc. (France)

Sponsor details
416, rue Samuel Morse
Montpellier Cedex 2
France
34961

Sponsor type
Industry

ROR
https://ror.org/018qejt38

Funder(s)

Funder type
Industry

Funder Name
Laboratoire Chauvin, Bausch & Lomb Inc. (France)

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