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Efficacy and safety comparison of a plant essential oil formulation vs traditional shampoo for Demodex ophthalmic infection treatment

Submission date
20/04/2015

Recruitment status
No longer recruiting

Registration date
30/04/2015

Overall study status
Completed

Last Edited
21/11/2016

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Demodex folliculorum is a mite found on the face, primarily near the nose, eyelashes and eyebrows, but they are also found in other places of the body. Infestations can cause skin problems, such as rosacea (resulting in facial redness, papules, pustules and swelling) and chronic blepharitis. Chronic blepharitis is an eye condition where the eyelid becomes swollen (inflamed). It is not a serious condition but can feel very uncomfortable and irritating, causing the eyes to feel sore and gritty. Demodex folliculorum can also cause demodicosis, the symptoms of which include eye irritation, dry eyes, itching, decreased vision and loss of eyelashes. One of the major limitations in the treatment of demodicosis is the difficulty in eradicating the mites that cause them. Some patients respond poorly to treatment with the continuing infection affecting their quality of life. A poor response to treatment may be due to the toxicity of some of the ingredients (for example, mercury) which means that they can only be used for a few weeks. Furthermore, the mites can become resistant to the treatment. The treatments offered may also not be specific to Demondex infection and destroy other bacteria in the skin. In this study, we want to test a highly specific biodegradable acaricide (drug that kill mites) formulation against Demodex folliculorum as a treatment for demodicosis and especially against blepharitis and keratoconjunctivitis (inflammation of the cornea and conjunctiva) caused by Demodex folliculorum infestation.

Who can participate?
Adults (aged at least 18) with a diagnosis of blepharitis acarida caused by Demodex folliculorum

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention) are given the new acaricide formulation. Those in group 2 (control) are given a placebo shampoo control formulation. Before treatment, all participants have gauzes presoaked in saline solution applied to their eyes (when closed) for five minutes; this allows greater penetration of the product being applied. A local anesthetic is also applied to each eye and a plastic protector placed over them before treatment begins. A gauze moistened with either the placebo or intervention formation is applied to the eyelid and eyelashes of each participant, replacing the

gauze with a clean one once debris has been seen on the gauze. The procedure is complete once no more debris can be seen on the gauze. The procedure is repeated for all participants every four days for 6.2 weeks. The participants are also asked to wash their sheets and pillows once every three days, not to share their linens, towels or pillows with anyone, avoid rubbing their eye with their hands and wash their hands several times a day. They are also asked to avoid bathing in the sea or a pool, not to use false eyelashes and not to use eye makeup. All participants are tested seven days after treatment begins and then again at 21 days for the presence of mites in their eyelashes.

What are the possible benefits and risks of participating?
Possible risks include mild pain or burning with removal of eyelashes, which disappear within a few seconds of removal. Any adverse side effects or allergic reactions will be dealt with immediately.

Where is the study run from?
Eye Clinic Caribbean (Clínica Oftalmológica del Caribe) (Colombia)

When is the study starting and how long is it expected to run for?
August 2014 to November 2015

Who is funding the study?
Laboratorios Procaps S.A (Colombia)

Who is the main contact?
1. Mr Gonzalo Nieto (public)
gnieto@procaps.com.co
2. Mrs Martha Lizarazo (scientific)
marthailiz2@hotmail.com

Contact information

Type(s)
Public

Contact name
Mr Gonzalo Nieto

ORCID ID
http://orcid.org/0000-0002-6855-4371

Contact details
Eye Clinic Caribbean (Clínica Oftalmológica del Caribe)
Calle 80 No 78B 201
Barranquilla
Colombia
080001
+573183501472
gnieto@procaps.com.co

Type(s)
Scientific

Contact name
Mrs Martha Lizarazo

Contact details
CLL 86 No. 50-158
Barranquilla
Colombia
080001
+5753363700
marthailiz2@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Production and evaluation of a formulation for prevention and treatment of blepharitis and keratoconjunctivitis caused by the ectoparasite Demodex Sp

Acronym
DMX

Study objectives
The plant essentials oils formulation is effective for Demodex sp ophthalmic infection treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North University Research in Health Ethics Board, Barranquilla Colombia, 23/02/2012

Study design
Double blind interventional open randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Demodex folliculorum

Interventions
1. Treatment administration:
The application of the magistral formula (FM) and the shampoo control treatment (ChB) will be in charge of the principal investigator. There won´t be difference according to the assigned intervention to the patient because the treatment will be masked to the ophthalmologist who applied; for this purpose the products commercial presentations and organoleptic properties will be adjusted, so that neither the patient nor the doctor could identify the treatment group.
The eyelids of the affected patients will be subjected in ophthalmologic clinic according to the modified rubbing technique. Prior to the application of treatment, gauzes impregnated with saline solution at 39 °C will be applied in closed eyes for five minutes, in order to cause dilation of the hair follicles of the eyelashes to allow greater penetration of the product being applied.
The topical local anesthetic Alcaine® 0.5% will be administered in each eye, at the rate of one drop per eye, and an eye plastic protector shall be placed in each eye, for protecting the eye during the procedure. A moistened gauze with placebo or the intervention will be used for rubbing the roots of the lashes with a rapid movement from one end to the other of the eyelid, at a constant pressure that causes the removal of deposited debris on the base of the eyelashes. Once the gauze meets debris, this one will be changed. This procedure will be repeated until no debris gauze, which usually occurs after 4 applications for each eyelid (upper and lower).
The time between changes of the gauzes is minimal, so the procedure may be considered as continuous. When there is no debris in the gauze, the procedure will be finished.
The procedure will be performed every four days using a protocol that will try to control all the stages of the parasite cycle and a total duration of 6.2 weeks
2. Associated interventions:
In both groups the recommendations of the ophthalmologist includes:
2.1. Wash sheets and pillows in hot water every third day
2.2. Do not share linens, towels or pillows
2.3. Avoid eye rub with hands
2.4. Wash hands several times a day
2.5. Avoid during treatment bath in the sea or pool
2.6. Do not use false eyelashes for the duration of the treatment
2.7. Do not share eye makeup or wear makeup outside during treatment
2.8. For users of contact lenses, remove them every time we come to the washing done
Since the treating physicians will be masked to allocation of intervention in both groups compared the same recommendations on the use of these concomitant interventions are made.

Visit 1 (basal state): After verifying the criteria for admission to study and obtain informed consent will be conducted subject some questions about their sociodemographic variables and you apply the instruments for measuring the variables of interest. A complete physical

examination including height and body weight will be performed. The baseline measurement of IP and EVA symptoms of blepharitis is performed. After the evaluation, implementation and random assignment to treatment group were prescribed and given an appointment for the first application.

Visit 2 (Day 0 treatment) (4 days after Visit 0)
First administration of treatment according to the group where he had been assigned. And collecting data on any news after treatment administration.

Visit 3 (Day 4 of treatment) (4 days after visit 2)
Second administration of treatment. And collecting data on any news after treatment administration.

Visit 4 (Day 8 of treatment) (4 days after Visit 3)
Third administration of treatment. And collecting data on any news after treatment administration.

Visit 5 (Day 12 of treatment) (4 days after the visit 4) Latest WASH
Fourth treatment administration. And collecting data on any news after treatment administration.

Visit 6 (Day 19 studio. one week after treatment ended)
Sampling, filling of forms for data collection. Post-treatment evaluation of the primary and secondary outcomes.

Visit 7 (Day 40 study, 21 STUDY, 21 days after the end of treatment
Sampling, filling of forms for data collection. Post-treatment evaluation of the primary and secondary outcomes.

Intervention Type
Supplement

Primary outcome measure
Demodex infestation index:
To determine the presence of mites 4 eyelashes per eye will be extracted under slit lamp with a watchmaker forceps, alternating between upper and lower eye lid. Once removed, the eyelashes will be mounted onto glass slide and observed in the CHT ® Olympus microscope with objectives 4x, 10x, 40x; the count is conducted with the objective of 4x and counted equally all stages of mite. Subsequently the parasite index mites/eyelash will be calculated by dividing the number of mites found on the total observed eyelashes. The IP will be considered positive if ≥ 0.5. The finding of 4 – 5 demodex mites will be interpreted as an intense parasite degree. The existence of a single mite in all eyelashes won't be interpreted as significant infection data.

In subsequent monitoring (day 7 and 21 post-treatment) only will be necessary to remove one eyelash per lid, 4 per evaluation. The growth of eyelashes is 21 days on average, a total of 20 eyelashes are used by patient.

Secondary outcome measures
Assessment of symptoms of blepharitis:
It will be evaluated through an 11 points analog visual scale (EVA), where zero (0) will represent the symptoms absence and ten (10) as the highest symptoms value. The instrument will be explained to the patients before its application.

Overall study start date
15/08/2014

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Men and not pregnant or lactating women ≥ 18 years of age
2. Blepharitis Acarida by Demodex sp clinical diagnosis
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
158

Key exclusion criteria
1. Current or recent (two weeks prior) treatment against Demodex sp
2. Oral or topic steroids consumption
3. Immunosuppressive disease medical history
4. Mental illness that does not allow an assessment of symptoms
5. Any illness that eventually requires hospitalization
6. History of malignant disease
7. Hypersensitivity to any of formulation ingredients

Date of first enrolment
04/05/2015

Date of final enrolment
04/09/2015

Locations

Countries of recruitment
Colombia

Study participating centre
Eye Clinic Caribbean (Clínica Oftalmológica del Caribe)
CLL 86 No. 50-158
Barranquilla
Colombia
080001

Sponsor information

Organisation
Laboratorios procaps S.A.

Sponsor details
Calle 80 No 78B 201
Barranquilla
Colombia
080001
+5753719103
gnieto@procaps.com.co

Sponsor type
Industry

Website
http://www.procapslaboratorios.com/

Funder(s)

Funder type
Industry

Funder Name
Laboratorios Procaps S.A

Results and Publications

Publication and dissemination plan
Planned publication of the study result in article on index journals just after the ending of this study. The publication will contain methodology, and the analyzed results of the comparative study.

Intention to publish date

28/02/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available