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Evaluation of the antimicrobial properties of Neosalus cream when applied to human skin

Submission date
28/11/2018

Recruitment status
No longer recruiting

Registration date
28/12/2018

Overall study status
Completed

Last Edited
18/01/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A defective skin barrier and bacterial colonization are two important factors in maintenance and progression of dry skin and eczema. The aim was to evaluate the antimicrobial efficacy of Neosalus cream.

Who can participate?
Healthy subjects at least 18 years of age of both genders who had normal skin that was free of disease and injury.

What does the study involve?
Upon completion of a 7-day product restriction period, a trained technician applied the test cream to the skin of one forearm. The other forearm received no test cream. Four sites were delineated on the skin of each forearm and, 10 minutes following the product application procedure, the sites were exposed to bacteria for contact times of 5 minutes, 10 minutes, 20 minutes, and 40 minutes. A collection liquid was then placed on the surface of the skin for one minute and then removed. The number of bacteria present in the collection liquid was then assessed in the laboratory. All participants received the same treatment.

What are the possible benefits and risks of participating?
There was nothing for the individual to gain from participating. No side effects were expected.

Where is the study run from?
The study was performed by Bioscience Laboratories, Bozeman Montana.

When is the study starting and how long is it expected to run for?
Study started 10/11/2009 – completed 29/03/2010

Who is funding the study?
Exceltis USA Dermatology

Who is the main contact?
Ruby Ghadially ruby.ghadially@ucsf.edu

Contact information

Type(s)
Scientific

Contact name
Prof Ruby Ghadially

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018-001

Study information

Scientific Title
Phase 1 of a Two-Phase Evaluation of the Antimicrobial Properties of Various Product Formulations

Study objectives
Neosalus Cream will have antimicrobial effects when applied to human skin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gallatin Institutional Review Board, 20/11/2009, ref. 090426-150.0

Study design
Single centre, blinded, within-subject, interventional

Primary study design
Interventional

Secondary study design

Within-subject

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dry skin

Interventions
Twenty subjects, ten subjects per group, were evaluated on the forearms to determine the efficacy of Neosalus by comparing the recoveries of Escherichia coli (ATCC #11229) and Staphylococcus aureus MRSA (ATCC #33593) bacteria from the skin of treated forearms to recoveries from the skin of untreated forearms.

After a 7-day product restriction period, a trained technician applied 1ml neosalus cream to the skin of one randomly assigned forearm. The left or right forearm was randomized to treatment with the test formulation, and the remaining forearm served as the untreated control. Following demarcation (see below), the four test sites of the skin of each forearm were assigned randomly and bilaterally to post-treatment sample times.

Four sites were delineated on the skin of each forearm and, 10 minutes following the product application procedure, the sites were exposed to the randomly assigned challenges of bacterial suspensions (Staphylococcus aureus or Escherichia coli 1.0 x 10E7 CFU/ml) for contact times of 5 minutes, 10 minutes, 20 minutes, and 40 minutes, and then sampled.

On completion of testing, subjects were required to perform a I-minute rinse of their forearms with 70% ethanol and an air¬ dry, followed by a supervised 4-minute wash with a 4% chlorhexidine gluconate solution. A topical antibiotic ointment was applied to the forearms following the decontamination procedure.

Intervention Type
Other

Primary outcome measure
Microbial counts recovered from subjects' forearms was measured using the Cylinder Sampling Technique at 5, 10, 20, and 40 minutes.

Secondary outcome measures
N/A

Overall study start date
10/11/2009

Completion date
29/03/2010

Eligibility

Key inclusion criteria
1. Healthy
2. Over 18 years old

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
20

Key exclusion criteria
1. Clinically evident dermatosis
2. Skin injury

Date of first enrolment
07/12/2009

Date of final enrolment
14/12/2009

Locations

Countries of recruitment
United States of America

Study participating centre
BioScience Laboratories, Inc. (testing facility)
300 N. Willson Avenue
Bozeman, Montana
United States of America
59715

Sponsor information

Organisation
(973) 324-0200

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Quinnova Pharmaceuticals, Inc

Results and Publications

Publication and dissemination plan
Planned publication in BMC dermatology (under review).

Intention to publish date
12/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from: Ruby Ghadially, ruby.ghadially@ucsf.edu, raw data, available by written request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		10/12/2018	10/12/2018	No	No

Results article	22/01/2019	18/01/2023	Yes	No