

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

Submission date 28/11/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/12/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/01/2023	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> 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

Contact details

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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 1.0×10^7 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 1-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

411 S. State Street, 3rd Floor

Newton

United States of America

18940

(973) 324-0200

ContactUsUSA@exeltis.com

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