PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Evaluation of the Efficacy to Accelerate Skin Repair after SDS-Induced Skin Irritation and Evaluation of the Protective Efficacy of Protective Cream WO 3133

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In this cosmetic study, the nourishing and protecting porperties of Protective Cream WO 3313 on artificially damaged skin of 30 healthy adults were tested. The cream was applied on one forearm of each subject for 14 days twice daily. Before and during the treatment, both forearms were thouroughly washed with a harsh washing solution in order to produce skin irritation. Hydration, redness and roughness of treated skin were measured and compared to untreated skin.

Brief Summary in Scientific Language

An artificial irritation of the skin by one week washing with sodium dodecyl sulfate (SDS) was performed to mimic epidermal barrier damage and to evaluate the regenerative and protective properties of Protective Cream WO 3313. Thirty healthy participants (17 female, 13 male; age: 44.2±8.3 years) were included in this intraindividual comparison study. The product was applied on the inner forearm for 14 days twice daily. Testing parameters were skin hydration, transepidermal water loss (TEWL), skin redness, and skin roughness. Untreated skin areas served as control.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

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DRKS-ID: **DRKS00009497**

- Date of Registration in DRKS: **2015/10/15**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]* , [Da es sich um eine Studie mit kosmetischen Mitteln handelt, deren Rohstoffe als sicher gelten, ist die Begutachtung durch eine Ethikkommission nicht zwingend vorgeschrieben. Somit wurde kein Ethikvotum beantragt.]**

Secondary IDs

Health condition or Problem studied

- Free text: **Epidermal barrier damage / skin irritation**

Interventions/Observational Groups

- Arm 1: **Test area: During the first phase (Day 1–7), the test area was washed once daily with 5% SDS solution. During the second phase (Day 9-14) the product (Protective Cream WO 3313) was applied twice daily and during the last phase (Day 15-21), the participants were asked to continue the product application procedure twice daily and to additionally wash the test area once daily with 5% SDS solution.**
- Arm 2: **Control area: During the first phase (Day 1–7) the control area was washed once daily with 5% SDS solution. During the second phase (Day 9-14) the area was not treated and during the last phase (Day 15-21) the participants were asked to wash the area once daily with 5% SDS solution.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Control group receives no treatment**

Purpose: **Treatment**

Assignment: **Other**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Skin regeneration in the test area compared to control area after SDS-induced irritation. Test parameters: skin hydration (Corneometer), transepidermal water loss (Tewameter), skin redness (Chromameter) and skin roughness (PRIMOS measuring system). Measurements: 12-14 hours after product application on day 10, 12, and 15.

Secondary Outcome

Skin protection against SDS-induced irritation in the test area compared to control area. Test parameters: skin hydration (Corneometer), transepidermal water loss (Tewameter), skin redness (Chromameter) and skin roughness(PRIMOS measuring system). Measurements: 5-6 hours after product application on day 17, 19, and 21.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Derma Consult Concept GmbH, Bonn**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/04/30**
- Target Sample Size: **30**
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Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2012/04/30**

Target Sample Size: **30**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Clinically healthy

Exclusion criteria

**Skin diseases,
pregnancy**

Addresses

- **Primary Sponsor**

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Fax: **[---]***
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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/05/21**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*