A study of biological, immunological and physiological parameters describing skin irritation induced by a physical stimulus in healthy male volunteers

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Primary objectivesTo study the relation between the physiological, microbiological and immunological status of the skin and the response to an external stimulus; to assess:• the relations between microbiome and/or immunology and the skin type;• the…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON38828

Source
ToetsingOnline

Brief title
Skin irritation induced by a physical stimulus

Condition

- Epidermal and dermal conditions

Synonym
skin irritation

Research involving
Human

Sponsors and support

Primary sponsor: TNO

Source(s) of monetary or material Support: TNO

Intervention

Keyword: Biopsy, Irritation, Microbiome, Skin

Outcome measures

Primary outcome

This study is explorative. The physiological, microbiological and immunological features of the skin will be assessed at time points, before and after an external stimulus to make comparisons between subjects with a sensitive and insensitive skin by measurement of the blood perfusion, and taking microbiome swab and biopsies (and additional tape stripping in study extension).

Adverse events, with emphasis on local skin irritation, will be recorded from screening until the end of the study.

Secondary outcome

Not applicable

Study description

Background summary

In more recent years it has become apparent that the microbiological status of the skin, the microbiome, may play a role in the homeostasis of the skin. The cutaneous innate and adaptive immune responses were found to be able to modulate the skin microbiota. In addition, the microbiota showed to have an effect on the immune system. Although, the microbiome of the skin needs further investigation to gain insight into microbial involvement in human skin disorders [5] associations between immunological diseases of the skin and population of the skin with certain bacterial strains, indicate that the microbiome may play an important role in the response of the skin to internal and external stimuli. Not much is known about the relationship between

microbiome composition and the inflammatory response to external or internal stimuli.

Study objective

Primary objectives
To study the relation between the physiological, microbiological and immunological status of the skin and the response to an external stimulus; to assess:
• the relations between microbiome and/or immunology and the skin type;
• the relation between the response to an external stimulus and microbiome;
• the relation between the response to an external stimulus and immunology;
• the relation between physiological parameters and immunology of the skin in response to an external stimulus;
• the relation between physiological parameters and microbiome of the skin in response to an external stimulus.

Secondary objectives
To assess inter-individual differences in response of the skin in terms of microbiology (microbiome) and immunology.

To design a model, describing the relationship between *the triangle* of skin irritation (skin physiological changes), immunological changes and microbiological changes.

To design a model to quantify inter-individual variations and identify biomarker variables that describe relationships and possibly causes of skin irritation given specific immunological and microbiological conditions.

Study design

This study has a controlled, open-treatment design.

The study consists of a screening, 1 study day of approximately 6 hours and two additional visits of 30 minutes on Day 3 and Day 8 for subjects participating in the study extension.

Study burden and risks

The risks associated with participation to this study are minimal. Obtaining biopsies have a potential small risk of leaving a minimal scar.

Contacts

Public
TNO

Utrechtseweg 48
Zeist 3704 HE
NL
Scientific
TNO

Utrechtseweg 48
Zeist 3704 HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Healthy male subjects, 18 to 65 years of age, inclusive;
2. Willing to undergo a shaving stimulus in the neck and upper leg;
3. Fitzpatrick skin type I-II-III-IV;
4. Last shave 24-36 hours prior to Day 1;
5. Used to electrical shaving;

Exclusion criteria

1. External use of isotretinoin within 3 months prior to or during this study, or oral use of isotretinoin (Accutane® or Roaccutance®) within 6 months prior to or during this study;
2. Coagulation problem or use of anticoagulation medicine, including the intensive use of

Aspirin, where no wash-out period of at least 1 week is taken into consideration;
3. Use of corticosteroids within 2 weeks prior Day 1;
4. Use of an antihistamine within 1 month prior to Day 1;
5. Epilepsy, lupus erythematodes, -porphyria;
6. Collagen defect in the past, including keloid wound (keloid accumulation or keloid scar formation), history of bad wound healing;
7. History with vascular diseases, like varicose veins in the area of treatment;
8. History of immune disease (including HIV positively or AIDS), or an autoimmune disease, use of medicine for immune/autoimmune diseases;
9. Treatment of any form of cancer (lately or in the past), history of skin cancer or other form of cancer in the area of treatment, present pre-malignant lesions;
10. Bad skin conditions on the area of treatment (like infections, open wound, scrape) or any other form of inflammation of the skin;
11. Surgical intervention in the area of treatment within 3 months prior to this study;
12. Sunburn in the area of treatment within 1 week prior to the study;
13. Big birthmarks, port wine stains, or other pigmentations in the area of treatment (>1cm2).

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43920.056.13