Tape stripping as a non-invasive in vivo model for mechanical skin damage

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In this project we would like to find out whether Sellotape stripped healthy skin can be used as an in vivo model for mechanical skin damage. This would contribute to more knowledge about growth, differentiation, inflammation and mechanical...

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

Summary

ID

NL-OMON37654

Source
ToetsingOnline

Brief title
Tape stripping as model for skin damage

Condition

- Epidermal and dermal conditions

Synonym
Skin damage, Skin irritation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van Economische Zaken;Landbouw en Innovatie en de provincies Gelderland en Overijssel

Intervention

Keyword: Model, RCM, Skin damage, Tape stripping

Outcome measures

Primary outcome

Parameters like amount of stratum corneum removal, epidermal thickness, influx of inflammatory cells and vascularisation will be studied. Further, the correlation between HE stained sections and RCM images will be investigated.

Secondary outcome

Not applicable

Study description

Background summary

Sellotape stripping is a commonly used standardized in vivo model for studying skin barrier function, epidermal growth and concurrent immune responses. It is not investigated whether this model can be used to study mechanical skin damage. Studying this, would increase the knowledge about mechanical disruption of the skin at biological and physiological level. In addition, this study would contribute to develop of skin friendly materials. Currently used testing methods, for example for testing artificial turf systems, do not simulate real sport related skin damage in vivo. Therefore, a non-invasive in vivo model by using RCM that simulates a real sport related injury would be of additional value. Besides obtaining knowledge about growth, differentiation, inflammation, pathology and damage of the skin, development of a non-invasive skin damage model would contribute to development of skin friendly materials and prevents biopsies in healthy volunteers in future research.

Study objective

In this project we would like to find out whether Sellotape stripped healthy skin can be used as an in vivo model for mechanical skin damage. This would contribute to more knowledge about growth, differentiation, inflammation and mechanical disruption of the skin.

Study design

This study is an explorative observational (descriptive) study.

Study burden and risks

The study population consists of healthy volunteers, entering the study does not lead to direct benefit for them. Before the volunteers will give informed consent/assent, we will inform them that attending in this research is not in any way beneficial to them. When the volunteer, despite of this, does wish to attend in this study, most likely he/she will do this to make a contribution to science. Considering this, we are of the opinion that a study with short follow-up and only minimal invasive techniques, is legitimate. Tape stripping and RCM imaging has been carried out by us in the past and has been proven to be painless and without any discomfort. Punch biopsies are taken according to standard procedures and may be slightly tender, scar formation does not occur or is barely visible.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

René Descartesdreef 1
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

René Descartesdreef 1
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adults between 18 and 65 years of age
Volunteers must be willing to give a written informed consent
Volunteers must be able to adhere to all requirements of the study
Volunteers must have skin type I, II or III, this will be evaluated together with a dermatologist

Exclusion criteria

Children or adolescents younger than 18 years of age
Volunteers with history or signs of chronic skin diseases
Volunteers with disturbed wound healing
Volunteers with relevant co-morbidities and medication
Volunteers exposed to large amounts of sunlight or UV-radiation in the last week

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2012

Enrollment:	186
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL40362.091.12