Suction blisters: induction time and level of blister formation in the skin

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON32796

Source
ToetsingOnline

Brief title
suction blisters

Condition

- Skin and subcutaneous tissue disorders congenital
- Epidermal and dermal conditions

Synonym
blisterdisease, skin disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: auto-immune blistering diseases, epidermolysis bullosa, induction time, suction blister

Outcome measures

Primary outcome

Induction time of suction blisters and level of blister formation in the skin

Secondary outcome

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Study description

Background summary

The department dermatology of the UMC Groningen is a specialised centre for patients with a blister disease. Research studies concerning congenital and auto-immune blister diseases made it a top reference centre in the Netherlands. This study concerns suction blisters, made on healthy subjects and on subjects with an blister disease. Because this is the first study in Groningen where we use suctioncblisters, it is the start of a whole new research topic in the excisting programme concerning blister diseases.

Study objective

With this study we want to validate the negative pressure instrument which can make suction blisters, so in the future it can be used for other purposes. It can be helpfull to study the effects of medication or other treatments on blister formation of the skin. Furthermore this study provides more information about the induction time of suction blisters and the level of blister formation in the skin in healthy subjects and subjects with an auto-immune blister disease.

Study design

Intervention study that, for a part, will take place on the polyclinic of the dermatology department in the UMC Groningen. Healthy subjects will be recruited in the hostipal, people who work here can voluntary participate in the study. They will be researchgroup 1. Patients known in the UMCG with a blister disease who fit the inclusion criteria will be send a letter en asked if they want to

participate in the study. These subjects will form researchgroup 2 and 3, depending on the type of blister disease they suffer from.
On all the subjects a suction blister will be made and induction times are recorded. Then a biopsy of the blister will be done in group 3, and the skin will be sutured to prevent infection of the wound. A protocol for the treatment of the wound will be made and applied. The biopsies are investigated in the immunodermatology laboratory of the UMCG, where the level of blister formation is recorded. The induction times and the level of blister formation will be compared between the three research groups.

Intervention

1. making a suction blister (diameter: 1cm)
2. local anaesthetic of the wound
3. biopsy (4mm) of the blister
4. suture of the skin (ethylon 5.0)

Study burden and risks

Subjects are asked to visit the polyclinic once, this visit will take about 60 minutes. Where possible, this visit will be combined with an excisting appointment with their own docter. If this is not possible, subjects can get a compensation for the costs they made to travel to the hospital.
After a biopsy there is always the risk of infection. To make this risk as low as possible, the wound will be sutured and a woudprotocol will be applied.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

group 1: healthy, age > 18 years, no skindisease or other disease that can influence blisterformation
group 2: patients with epidermolysis bullosa, age >18 years
group 3: patients with auto-immune blisterdisease, age >18 years

Exclusion criteria

group 1: people with a blisterdisease or an other disease that can influence blister formation, age < 18 years
group 2: age < 18 years
group 3: age < 18 years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	negative pressure device
Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL25089.042.08