IgG response against Staphylococcus aureus in patients with Netherton syndrome

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Primary objectives:To evaluate the pathogen host interactions between S. aureus and NS patients:o IgG and IgG4 responses against S. aureus antigens in NS patients will be compared with IgG and IgG4 responses against antigens of other bacteria (e.g....

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

Summary

ID

NL-OMON53242

Source
ToetsingOnline

Brief title
IgGNS

Condition

- Epidermal and dermal conditions

Synonym
Comel-Netherton Syndrome, Netherton Syndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: IgG, Netherton syndrome, SPINK5, Staphylococcus aureus

Outcome measures

Primary outcome

- IgG antibody levels against S. aureus antigens, and a panel of other bacterial antigens (e.g. Pseudomonas aeruginosa, Streptococcus pneumoniae) measured in serum of NS patients using a Luminex assay, and compared to IgG antibody levels in healthy S. aureus carriers and non-carriers, AD patients and EB patients.

- A list of S. aureus proteins produced in the skin of NS patients.

Secondary outcome

- Differences in IgG and IgG4 antibody levels in NS patients over time.

- Identification and characterization of S. aureus (skin and nose) in NS patients.

Study description

Background summary

Netherton syndrome (NS) patients frequently experience skin infections and the presence of Staphylococcus aureus (S. aureus) on the skin and mucosa of these patients has been described in multiple studies. Little is known about the strategies used by the bacteria to colonize and interact with the patients skin/local immune system. To understand this pathogen host interaction better we want to investigate which proteins are made by the bacteria and the immunological countermeasures of the host.

Study objective

Primary objectives:
To evaluate the pathogen host interactions between S. aureus and NS patients:

o IgG and IgG4 responses against S. aureus antigens in NS patients will be compared with IgG and IgG4 responses against antigens of other bacteria (e.g. Pseudomonas aeruginosa, Streptococcus pneumoniae) to determine whether NS patients respond differently towards S. aureus then other bacteria in comparison to healthy S. aureus carriers and non-carriers, AD patients and EB patients.
o Local production of S. aureus proteins will be studied by performing proteome analyses on NS skin biopsies.

Secondary objectives:
o To evaluate changes in the IgG and IgG4 responses in NS patients over time
o To assess and characterize the cultured (skin and nose) S. aureus isolates in NS patients using several techniques

Study design

This is an explorative observational study. Collection of all control group data is not part of the current study protocol.

Study burden and risks

Risks assessment: Blood drawing is a routine clinical procedure and is generally safe, besides the risk of a local hematoma after blood collection. Taking swabs is non-invasive and is not associated with specific risks. Filling in the questionnaires may take some time for the patient. The skin biopsy is optional. A skin biopsy is a routine dermatological procedure and is generally safe, however there is a small risk of bleeding, infection and/or a small scar.
Benefits and group relatedness: patients will not directly benefit from the study. However, participation in the study will generate new knowledge on the pathogen host interaction in NS which will be beneficial to the scientific community worldwide and accelerate the search for therapeutic strategies for NS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- Diagnosed with NS by an expert professional
- Aged 16 years or above
- Able to read patient information, fill out questionnaires and provide informed consent

Exclusion criteria

- Systemic antibiotics within the previous 4 weeks
- Topical antibiotics within the previous 7 days

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):	22-11-2023
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	16-11-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL85267.078.23