Pathogenic cells and mediators involved in chronic inflammatory skin diseases

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Determine the frequency, phenotype and function of disorder-related immune cells, or levels of immune molecules in skin and peripheral blood of patients with inflammatory skin diseases, during the active phase of disease prior to and/or at any time...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON49586

Source
ToetsingOnline

Brief title
Pathogenic cells in inflammatory skin diseases

Condition

- Allergic conditions
- Epidermal and dermal conditions

Synonym
chronic inflammatory dermatitis, longlasting skin inflammation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cytokines, inflammation, lymphocytes, skin

Outcome measures

Primary outcome

1. To identify the key pathogenic cells, their function, interaction and production of mediators (e.g. cytokines, chemokines) in inflammatory skin diseases and to recognize the role of these parameters in the etiopathology and to what extent they are specific for the different disorders.

2. To assess if the identified putative pathogenic cells are also present in asymptomatic skin of the same patient (or persist after therapy) or in healthy normal human skin. If so, the question needs to be answered why these cells are only locally triggered to cause the disease (e.g. higher quantity of pathogenic cells, presence of activation factors).

3. To assess if the presence of identified putative pathogenic cells and mediators correlate with therapy (do they decline in responders and persist in non-responders), and determine whether different treatment modalities have differential potential to change the frequency and functional state of those pathogenic cells and mediators.

4. To identify key disease-specific biomarkers (genetic and protein level) in blood or skin samples that can accurately predict disease progression or therapeutic response at an early stage and independent of the therapy modality used.

Secondary outcome

not applicable

Study description

Background summary

Inflammatory skin disorders (including psoriasis, atopic dermatitis, lichen planus, and contact dermatitis) are related to aberrant function or imbalanced interaction of immune cells in the skin and may have an (epi)genetic cause. The majority of patients with inflammatory skin diseases is successfully treated with standard therapies, yet current treatments (including biologics for psoriasis and atopic dermatitis) appear not effective in a substantial number of patients for unknown reasons. Hence, dermatologists would like to know as early as possible (preferably a priori) whether the applied treatment (or considered therapy) would provide a good outcome, in order to prevent unnecessary exposure to ineffective drugs and their side effects and delay effective treatment with alternative drugs. Therefore, the responsiveness to a drug (in particular expensive biologics) should be determined as soon as possible, to refrain nonresponders from that drug at an early stage, and to keep medical care affordable. Accordingly, there is a high unmet medical need for identification of biomarkers that can inform which therapies are most likely to be efficacious for a particular patient. In addition, uncovered key biomarkers may serve as new targets to improve therapeutic intervention.

Study objective

Determine the frequency, phenotype and function of disorder-related immune cells, or levels of immune molecules in skin and peripheral blood of patients with inflammatory skin diseases, during the active phase of disease prior to and/or at any time under treatment. These data will be compared to corresponding cells and mediator levels in healthy controls, to understand their role in the development and resolution of the disease. This study will identify predictive biomarkers for therapeutic outcome.

Study design

Single center, longitudinal, observational study

Study burden and risks

Subjects participating in the study will not experience any delay, disadvantage in their medical care nor miss any regular treatment.
Risks associated with skin biopsy taking are bleeding, infection, and scar formation, all of which are negligible because of the small size of the biopsy. Vena puncture to draw blood may result in a temporary hematoma at the site of puncture. Vacuum-mediated sampling of skin fluid from laser-created micro-pores is optional and requires a time investment of around two hours. There is a

limited risk of blister formation due to the vacuum-assisted fluid sampling, the sampling area is known to heal without scar tissue and the risk of infection is negligible. Tape-stripping and saliva sampling are simple, painless and quick procedures.
The results of this study will have no direct impact on the patient*s treatment. However, it is important to remember that the knowledge gained may have an impact on our future practice in the treatment of inflammatory skin diseases.

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

Adult (age >=18) patients with inflammatory skin disorders: psoriasis, atopic

dermatitis, lichen planus, or (irritant, allergic, or photo) contact dermatitis

Exclusion criteria

Patients with hypertrophic scars, with keloid, with a history of hypersensitivity or allergy to local anesthesia, and patients with hemophilia or other clotting disorders.

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):	23-02-2021
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	16-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2020

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL72248.018.19