The role of (micro)vasculature and angiogenesis in inflammatory diseases of the human skin

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

Summary

ID

NL-OMON40712

Source
ToetsingOnline

Brief title
(micro)vasculature and angiogenesis in inflammatory skin diseases

Condition

- Epidermal and dermal conditions

Synonym
psoriasis, red scaly skin disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Angiogenesis, Endothelial cell, Inflammatory disease, Psoriasis

Outcome measures

Primary outcome

The main goal of this study will be an extensive evaluation of the microvasculature and angiogenesis in different phases of psoriatic disease and in uninvolved skin of psoriatic patients. In this manner more knowledge regarding angiogenesis and its impact on psoriatic lesion development, maintenance and remission of this inflammatory skin disease is to be expected. Biopsies will be processed and tissue sections will be analyzed for the presence of angiogenesis and the extent of the MVD, using immunohistochemistry (IHC) and immunofluorescence (IF). The tissues will be stained with markers for Endothelial Cells (ECs) and markers for cell proliferation and inflammation. The tissues will be visualized using microscopy, photographed and analyzed using computer software (Image J).

Secondary outcome

Subsequent to this (pilot) study, the relation of angiogenesis in relation to other key processes in inflammatory skin disease (i.e. recruitment of immune cells, cytokine levels, pro- and anti-angiogenic factors and epidermal proliferation) will be analyzed.

Study description

Background summary

Currently there is little known of the role of angiogenesis in inflammatory skin diseases, such as psoriasis; i.e. the factors that trigger or diminish angiogenesis and the moment in which angiogenesis starts or stops. One of the earliest events in the development of psoriatic plaques is a vascular network expansion, which occurs before epidermal changes. Aberrant dilated capillary loops have frequently been found in normal looking skin of psoriatic patients. So angiogenesis may not only be a cofactor but also an inducer of psoriatic development.
More knowledge about the role of angiogenesis in psoriasis could lead to exciting new explanations for the induction and support of inflammatory pathologies, such as autoimmune disease and chronic inflammation. In this project we will focus on the microvasculature and angiogenesis in different phases of psoriasis and in uninvolved skin of psoriatic patients.

Study objective

In this project we would like to answer the following questions:
To what extent are increased micro-vessel density (MVD) and excessive angiogenesis in inflammatory skin diseases observed during different phases of the disease (i.e. acute/ exacerbation phase, chronic phase, remission phase and uninvolved skin of for example psoriasis patient).
What can be learnt from the diversity in MVD and angiogenesis during different phases of psoriasis?

Study design

This study is an explorative observational study; starting with a pilot (n=10) study to evaluate the margin of spreading in (micro-)vasculature in and within psoriatic lesions. An additional 50 patients will be included in the study to analyze the dynamics of treatment (i.e. photo therapy, TNF-inhibitors, dithranol and clobetasol 17-proprionate) on the vasculature.

Study burden and risks

Patients with psoriasis will be screened and asked for informed consent before participating in the study. Patients entering the study do receive the same regular patient care and treatment-regimens as patients who do not enter the study. All patients entering this study will receive extra procedures, involving physical examinations and punch biopsies. Biopsies will be taken at different stages of the disease (i.e. acute/exacerbation, chronic, remission phase) and from symptomless skin adjacent to the lesion(s) and from the distant uninvolved skin. The punch biopsies will be taken according to standard procedure and may be slightly sensitive. Scar formation does not occur or is barely visible; occasionally the appearance of a psoriatic papule (3mm) at the site of little trauma may occur and can easily be treated with a topical

corticosteroid.

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

Patients must meet the following criteria:
- Adults older than 18 years of age
- All patients have tot have chronique plaque psoriasis (i.e. psoriasis vulgaris)
- Patients must be willing to give a written informed consent
- Patients must be able to adhere to the visit schedule
- Applicable in fifty patients; The doctor and the patient decided that the best treatment option was photo therapy, clobetasol 17-proprionate, dithranol or anti-TNF treatment;Criteria voor vrijwilligers:
- Adults older than 18 years of age

- Volunteers must be willing to give written informed consent
- Volunteers must be able to adhere to the visit schedule

Exclusion criteria

Patients will be excluded from this study when any of the following criteria listed below are met:
- Children or adolescents younger than 18 years of age
- Patients with relevant co-morbidities
- Patients with another subtype of psoriasis than psoriasis vulgaris
- Patients with a history of signs of other (inflammatory) skin diseases, for example atopic dermatitis
- Patients who use medication with inhibitory effects on angiogenesis (for example Thalidomide (Softanon®), Sunitinib (Sutent®), COX-2 inhibitors as NSAIDs)
- Patients with co-morbidity that positively or negatively affects angiogenesis (such as microangiopathy and/or peripheral vascular disease in diabetics, smokers, etc)
- Use of anti-psoriatic medication before inclusion:
- Topical medication in the last 7 days
- Systemic medication or photo therapy within the last 4 weeks
- Patients with multiple (superficial) wounds and excoriations
- Patients with contra-indications for any kind of psoriatic treatment;Exclusion criteria for Healthy volunteers:
- Children or adolescents younger than 18 years of age
- Volunteers with relevant co-morbidities
- Volunteers with a history or signs of other (inflammatory) skin diseases, for example atopic dermatitis and psoriasis
- Volunteers who use medication with inhibitory effects on angiogenesis (for example Thalidomide (Softanon®), Sunitinib (Sutent®), COX-2 inhibitors as NSAIDs)
- Volunteers with co-morbidity that positively or negatively affects angiogenesis (such as micro-angiopathy and/or peripheral vascular disease in diabetics, smokers, etc)
- Volunteers with multiple (superficial) wounds and excoriations

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:	Recruitment stopped
Start date (anticipated):	09-02-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	02-12-2014
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	NL50490.091.14