Psoriatic Arthritis Atopy Study Eindhoven Rotterdam

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON33653

Source
ToetsingOnline

Brief title
APASER-study

Condition

- Joint disorders
- Cornification and dystrophic skin disorders

Synonym
arthritis due to psoriasis, arthritis psoriatica

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: atopy, psoriatic arthritis, reumatoid arthritis, Th1/Th2-mediated disease

Outcome measures

Primary outcome

1. Prevalence of Th2-cell mediated disease as asthma, allergic rhinoconjunctivitis, atopic dermatitis and hand eczema in groups of patients with psoriatic arthritis, rheumatoid arthritis, cutaneous psoriasis, melanocytic naevi and phlebological problems.

4. Results of tests of total IgE, RAST inhalation allergies, Th1, Th2 and Th17 cytokines and genetic variation in genes coding for these cytokines in groups of patients with psoriatic arthritis, rheumatoid arthritis, cutaneous psoriasis, melanocytic naevi and phlebological problems.

Secondary outcome

Quality of life and (subjective) general health in groups of patients with psoriatic arthritis, rheumatoid arthritis, cutaneous psoriasism, melanocytic naevi and patients with a phlebological problem.

Study description

Background summary

Psoriasis is a common, non-contagious skin disease with red flaking patches. Approximately, 1.5% of individuals in western European countries and the US has this skin disease (point prevalence).
In 5 to 42% of these individuals, arthritis occurs, especially of the smaller joints of hands and feet. In 68% of cases, this so-called psoriatic arthritis is preceded by signs of cutaneous psoriasis with a mean period of 10 years. In

14 to 21%, joint symptoms do occur first. Sometimes (15%), both arthritis and skin psoriasis do present at the same time.

The exact etiology of psoriasis is unknown. Genetics plays an important role. In those individuals prone to develop cutaneous psoriasis, symptoms can be provoked by infections, certain drugs, UV-exposure, hormonal influences, psychological stress, alcohol abuses and smoking.

Recent hypothesis indicate that a dysbalans of regulator T cells is responsible for the occurrence of psoriasis. Regulator T cells consist of two groups of cells: Th1-cells involved in the production of the cytokines IL-2, IFN-γ and IL-12 and Th1-cells associated with the production of IL-4, IL-5 and IL-10. Psoriasis is assumed to be a example of a Th1-cell mediated disease. Examples of Th2-cell mediated diseases are asthma, allergic rhinoconjunctivitis, atopic dermatitis, hand eczema, bullous pemphigoid and HIV-positivity. What pleads for this hypothesis, is the fact that psoriasis/psoriatic arthritis is seldom seen in patient who had atopic dermatitis in childhood.

Study objective

Aim of this study is to explore the relation between Th1-cell mediated diseases as psoriasis/psoriatic arthritis and Th2-cell mediated asthma, allergic rhinoconjunctivitis, atopic dermatitis and hand eczema. Question is whether a dysbalans in regulator T cell population in favor of Th1-cells does protect against Th2-cell mediated disease.

Study design

Prospective study in a group of 700 patients, namely men and women aged 18 years and over with psoriasis, psoriatic arthritis, rheumatoid arthritis (controls), melanocytic naevi and patients with a phlebological problem who consult the reumatologist and/or dermatologist.

Study burden and risks

Both burden of the study and risks associated with participation are extremely low. Consultations are combined with regular visits to the different departments involved. Blood testing seldom causes asymptomatic bruises in the elbow.

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

Participant is 18 years or older
Participant gives written consent for the prospective study
Participant is willing and able to complete different questionnaires in Dutch language
Participant agrees with blood testing for allergy (Total IgE, RAST inhalation allergy, serum cytokines and cytokine genes)

Exclusion criteria

Participant is 17 years or younger
Participant refuses blood testing for allergy
Participant is pregnant or gives breastfeeding

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:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	700
Type:	Anticipated

Ethics review

Approved WMO Date:	16-08-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-02-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-06-2009
Application type:	Amendment
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	NL13943.078.07