

# **\*Exploring cytokine detection in the stratum corneum of psoriasis patients by two noninvasive methods: sampling by TAPE and Transdermal Analysis Patches (TAP).\***

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(I) To compare patient friendliness in adult psoriasis patients between two non-invasive cytokine detection methods: TAP and TAPE. (II) To assess the correlation in cytokine detection by TAP and TAPE stratum corneum sampling in psoriasis patients.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Epidermal and dermal conditions
<b>Study type</b>	Observational non invasive

## **Summary**

### **ID**

NL-OMON49846

### **Source**

ToetsingOnline

### **Brief title**

Cytokine detection in the stratum corneum in psoriasis

### **Condition**

- Epidermal and dermal conditions

### **Synonym**

Psoriasis

### **Research involving**

Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cytokines, non-invasive, psoriasis, skin

## Outcome measures

### Primary outcome

The main study endpoints are the Visual Analogue Scale (VAS) scores and the levels of cytokines measured by both TAP and TAPE procedure. The two VAS score (VAS-TAP and VAS-TAPE) will be used to study the possible discomfort and perception of patients by the removal of the TAP and the TAPE.

### Secondary outcome

Not applicable.

## Study description

### Background summary

Although the majority of psoriasis patients can be sufficiently treated with topical agents, some patients need more intensive or aggressive treatment such as systemic treatment or biologics. Initiating such treatment early-on in this group of patients might positively influence their course of disease and quality of life. Identifying or predicting the course of disease of an individual would enable us to give the appropriate treatment timely. Therefore, we are searching for biomarkers that could predict the natural course of psoriasis or (systemic) treatment response per individual patient. To minimize the burden on patients and maximize the implementation potential, we are searching for non-invasive methods to detect such biomarkers. Two non-invasive methods, Transdermal Analyses Patches (TAP) and sampling of the stratum corneum by adhesive tapes (TAPE), are able to measure cytokines or other soluble factors deposited in the stratum corneum of the skin that might serve as biomarkers. Although both methods are non-invasive, patients\* perception of these two methods and their applicability in daily clinical practice might

differ. We therefore seek to evaluate possible differences in patient friendliness of both methods. In addition, we aim to assess the correlation between the protein detection of both methods.

## **Study objective**

(I) To compare patient friendliness in adult psoriasis patients between two non-invasive cytokine detection methods: TAP and TAPE. (II) To assess the correlation in cytokine detection by TAP and TAPE stratum corneum sampling in psoriasis patients.

## **Study design**

An explorative, observational, non-invasive pilot study of protein detection in the stratum corneum by two methods (TAP and TAPE) in adult psoriasis patients at one timepoint during a regular outpatient clinic visit.

## **Study burden and risks**

There are no immediate benefits for subjects participating in the study, but this study enhances the knowledge on non-invasive methods to detect biomarkers in the skin. This study will be incorporated in daily clinical practice.

Patients participating in this study will have their regular outpatient visits and no extra visits so that the burden for the participating patient is minimized. During the regular visit, first one TAP will be applied for 20 minutes and thereafter a TAPE procedure will be performed. Some transient mild erythema can be observed directly after collecting the TAPES, but as the barrier function of the skin stays intact with this procedure, it will not result in local skin irritation, scarring or post inflammatory hyperpigmentation. Given the non-invasive nature of both the TAP and TAPE procedures we estimate the study risks as \*negligible\*. Furthermore, given the short application time (20 minutes) with application during regular visits at one timepoint, we consider participation in this study acceptable.

## **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**

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- \* Age \* 18 years.
  - \* Willing to sign the informed consent.
  - \* Diagnosis of psoriasis according to a dermatologist.
  - \* At least 1 psoriasis plaque with a sufficient total surface of at least 2.5cm x 3.5cm in order to execute TAP and TAPE procedure within one lesion.
- Alternatively, 2 psoriasis plaques on the same body region with a similar SUM score with a total combined surface of at least 2.5cm x 3.5cm may be used.

### **Exclusion criteria**

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- \* No diagnosis of psoriasis.
- \* Diagnosis of other inflammatory skin disease.
- \* Not willing to participate or sign informed consent.
- \* Not willing to stop topical treatment on the day of sampling.
- \* Age <18 years.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 22-09-2020

Enrollment: 10

Type: Actual

## Ethics review

Approved WMO

Date: 12-05-2020

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

CCMO

### ID

NL73363.091.20