

# Cross-sectional study on determinants of contact dermatitis on the hands of construction workers: etiologic studies and development of a diagnostic tool

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Skin and subcutaneous tissue disorders congenital
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON39572

### Source

ToetsingOnline

### Brief title

Dermatitis in the construction industry: determinants and faster treatment.

### Condition

- Skin and subcutaneous tissue disorders congenital
- Allergic conditions
- Epidermal and dermal conditions

### Synonym

contact dermatitis; hand eczema

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit Utrecht

**Source(s) of monetary or material Support:** Stichting Arbouw

## Intervention

**Keyword:** construction workers, diagnostic tool, etiology, hand dermatitis

## Outcome measures

### Primary outcome

\* Occupational contact dermatitis (diagnosed by a team of a dermatologist and an occupational physician) is the main endpoint of the study.

Other main study parameters are:

- \* Contact dermatitis as diagnosed using a questionnaire
- \* Atopic status (specific serum IgE to a panel of common allergens)
- \* Mutations in the filaggrin gene (R501X, 2282del4, R2447X, S3247X, 3702delG)

### Secondary outcome

Risk factors/predictors for OCD will be obtained by questionnaire. Questions will be asked on smoking status and a number of airway diseases that could be related to (atopic) dermatitis. In addition, questions are included on exposures to various products (e.g. paints, solvents, cement, etc.) to evaluate the risk of working with these products to realize the Stoffenmanger skin extension.

## Study description

### Background summary

Occupational contact dermatitis (OCD) is one of the most prevalent occupational

diseases in many countries and accounts for more than 95% of all occupational dermatoses. In the general population, hand dermatitis prevalence is estimated to be around 4%. Recently, we analyzed data from a questionnaire that is administered as part of a regular program of voluntary occupational health examinations (PAGO). Amongst 110,024 construction yard workers, skin symptoms on the hands or fingers were reported by 25%. Dermatitis symptoms are very intermittent, making diagnosis challenging. However, as ongoing exposure may lead to chronic OCD, it is of outstanding interest to diagnose OCD at an early stage and to offer specialized health care to prevent OCD from becoming chronic.

## **Study objective**

Primary objective is to determine the actual occurrence of and risk factors for OCD on the hands of Dutch construction workers.

With these new insights into the risk factors for OCD, we aim to develop 1) a new diagnostic tool to be used by occupational physicians to screen construction workers for predictors of OCD, and 2) a predictive tool for companies to assess the risk reduction, for instance by implementing protective measures.

The first is a triage tool to diagnose construction workers with OCD. It is meant to be used by occupational physicians to identify workers with a high risk for having OCD. They can then be referred to a specific health care provider, i.e. a (occupational) dermatologist. The second tool is an extension of the \*Stoffenmanager Bouwnijverheid\* which is to be used by construction companies. It is meant to register hazardous substances and products and to propose safer working methods with those substances. The planned extension is focused on contact dermatitis and the risks of material handling and the risk reduction by implementing protective measures.

## **Study design**

Observational cross-sectional study among 1000 construction workers.

Participants will be enrolled

- 1) while attending a regular program of voluntary occupational health examinations (PAGO), or
- 2) during a visit at construction companies.

Participants will fill in a questionnaire, either digitally or on paper. Photos of the hands will be made, which will be diagnosed on OCD by a team consisting of a dermatologist and an occupational physician. Blood will be collected via venapunction to determine atopic status and to genotype loss-of-function mutations in the FLG gene.

## **Study burden and risks**

For subjects attending the PAGO: as the study takes place within the regular

medical check-up, participation does not yield any risk for the study participants. Two extra blood tubes (1 \* 6 mL and 1 \* 4 mL) will be collected, but no additional venapuncture is required. For subjects participating at the toolbox meetings: two blood tubes (1 \* 6 mL and 1 \* 4 mL) will be collected via venapuncture. The risks related to venapuncture are negligible. Participation in the study will take around 20-25 minutes of time. Possible benefits for participants and other construction workers are a greater chance of diagnosing current skin disease, prevention of potential chronic OCD, as well as a better awareness of the existence of skin disease and harmful dermal exposures in the construction industry.

## 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

Construction workers

## Exclusion criteria

office personnel

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 05-03-2014

Enrollment: 1000

Type: Actual

## Ethics review

Approved WMO

Date: 04-03-2014

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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**

<b>Register</b>	<b>ID</b>
CCMO	NL42457.041.13