Prevalence of latex allergy among operating room employees in the Netherlands

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Research questions:What is the current prevalence of latex allergy among operating room employees from Erasmus Medical Centre, Rotterdam? Is the sensitisation prevalence significantly lower compared to the prevalence before introducing non powdered…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ocular infections, irritations and inflammations
Study type	Observational invasive

Summary

ID

NL-OMON32458

Source
ToetsingOnline

Brief title
latex allergy among operating room employees in the Netherlands

Condition

- Ocular infections, irritations and inflammations
- Respiratory disorders NEC
- Angioedema and urticaria

Synonym
job related allergy, work related allergy

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: allergy, latex, occupational, operating room

Outcome measures

Primary outcome

Prevalence of sensitisation to latex, prevalence of work related

rhinoconjunctivitis, asthma

and skin complaints after contact with latex.

Secondary outcome

n/a

Study description

Background summary

In the present situation, latex hypersensitivity among healthcare workers is a well-known and acknowledged occupational disease. An IgE mediated allergy to latex can induce reactions ranging from (work related) urticaria and rhinoconjunctivitis to asthma and even anaphylactic shock and is therefore a serious health problem. Health care workers are especially at risk due to their frequent contact with rubber gloves.

Powder (from maize meal) in powdered NRL gloves plays an important role in the sensitisation process in glove wearing employees, since latex allergen can bind to it. When this powder subsequently becomes airborne, employees are exposed to latex allergen and sensitisation can occur via inhalation.

The use of protective gloves by health care workers has increased since the era of acquired immunodeficiency syndrome (AIDS). This increase has led to numerous undesirable cutaneous and mucosal effects, such as IgE mediated reactions. In the 1990s, the prevalence of NRL allergy in health care workers had been estimated at up to 40%.

In a systematic review published in 2006, natural latex allergy was found in 4.32% of health care workers. The decrease in new cases has been attributed to an overall reduction in NRL exposure by introduction of low-allergen (often powder-free) NRL gloves or allergen free non NRL gloves in health care facilities.

In 1997 and 1998, two studies on the prevalence of latex allergy among Dutch health care workers regularly wearing NRL gloves have been performed. Both studies were carried out in Erasmus Medical Centre, Rotterdam. These studies, among employees of the immunology department on the one hand and the operating rooms on the other hand, showed prevalence figures of respectively 8.3% and 14.1%.

In order to reduce the sensitisation prevalence among Erasmus Medical Centre employees, the board of Directors changed the hospital glove policy: In 1998 powdered research NRL gloves were replaced by non powdered NRL gloves and 1 year after, the same replacement was realized for sterile surgical NRL gloves.

Study objective

Research questions:
What is the current prevalence of latex allergy among operating room employees from Erasmus Medical Centre, Rotterdam? Is the sensitisation prevalence significantly lower compared to the prevalence before introducing non powdered sterile surgical NRL gloves for operating room employees?

Study design

Study design:
Glove wearing operating room employees from Erasmus Medical Centre, (n = 328) older than 18 years will be asked to participate. Biographic data, data on job characteristics and (work related) respiratory symptoms will be gathered by means of a questionnaire. Also skin prick tests with allergen extracts will be performed including a latex extract from a surgical glove and commercial available latex (soluprick ALK 960), cross reacting foods such as kiwi, avocado, banana and common inhalalant allergens. Additionally, blood samples will be taken for additional recombinant RAST tests.

Study burden and risks

Burden and risks:
A systemic severe reaction after a skin prick test (an allergic reaction to the skin test) is rare, because only a minimum amount of allergen is used. Local itchiness can occur. Apart from the direct skin reaction (after 15 minutes) an itchy swelling can appear after 6 hours. This swelling will disappear in the next few days.

The duration of the visit amounts approximately 30 minutes.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Burgemeester s' Jacobplein 51
3000 CA Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Burgemeester s' Jacobplein 51
3000 CA Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Glove wearing operating room employees from Erasmus Medical Centre, Rotterdam older than 18 years.

Exclusion criteria

If an employee is not able to stop his antistamine medication for 3 days prior to the investigation, the employee concerned can not participate in the study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-11-2008
Enrollment:	328
Type:	Actual

Ethics review

Approved WMO

Date:	06-11-2008
Application type:	First submission
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	NL24309.078.08