Effect of oat-coated disposable gloves compared to non-coated disposable gloves, in health care workers, with high glove consumption, on skin condition and user experience.

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Usability of oat-coated gloves (intervention) and the effect on skin condition in comparison to non-coated gloves (care as usual).

Ethical review	Approved WMO
Status	Pending
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON57130

Source
ToetsingOnline

Brief title
COAT

Condition

- Epidermal and dermal conditions

Synonym
hand dermatitis, hand eczema

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Hartalega

Intervention

Keyword: hand eczema, health care workers, oat, prevention

Outcome measures

Primary outcome

The main study parameters are the prospective analysis of skin condition of the hands of the HCW and their user experience. The primary endpoint is the difference in change in Osnabrück hand eczema severity index (OHSI), from baseline to 6 months between HCW using the oat coated gloves (intervention group) and HCW using non-coated gloves (care as usual group.

Secondary outcome

Secondary endpoints are the difference in patients reported outcomes (Quality of Life in Hand Eczema Questionnaire (QLHEQ), user experience questionnaire-short version (UEQ-S)) between groups. Furthermore differences in Trans Epidermal Water Loss (TEWL), skin hydration, skin erythema and levels of inflammatory cytokines and natural moisturizing factors (NMF) in tape strips are measured between the intervention and control group.

Study description

Background summary

Hand eczema (HE) is the most common occupational skin disease. (1) In particular employees in professions with frequent use of disposable gloves suffer from work-related hand eczema. (2-4) As a consequence of the mandatory

frequent use of disposable gloves, 30 - 60% of nurses adhering to the hygiene guidelines suffer from irritant contact dermatitis (ICD) of the hands. (5, 6) This highlights the need for a disposable glove that is less skin-irritating or, preferably, has skin condition-improving capacities to prevent occupational HE.

Study objective

Usability of oat-coated gloves (intervention) and the effect on skin condition in comparison to non-coated gloves (care as usual).

Study design

Single center, double-blind randomized controlled trial. Health care workers (HCW) will be randomized to the intervention group (oat coated gloves) or the care as usual group (non-coated gloves) for a period of six months. Because of practical considerations HCW will be randomized by department in the intervention or control group.

Intervention

HCW in the intervention arm will receive disposable nitrile examination gloves with an oat coating and HCW in the care as usual arm will receive non coated disposable nitrile gloves, as HCW currently use. The coating on the inner side of the glove consist of colloidal oatmeal to protect the skin underneath the glove. The oat coating is not visible and when taking off the glove no oat residue remains on the skin. The HCW perform their regular daily work activities.

Study burden and risks

The burden and health risk for the HCW associated with participation is negligible. The oat coating is the only difference between the current disposable examination gloves used in the hospital and the intervention gloves. A potential risk is the development of an allergy to oats, which is extremely rare. Patients known with an oat allergy will be excluded. Subjects perform their regular daily work activities. To date, no allergic reactions to oat coated gloves have been reported to Lareb and The Health and Youth Care Inspectorate (IGJ). The skin condition of the hands of the participating HCW will be examined by a physician at baseline and three times during the treatment period of 6 months. Questionnaires about baseline characteristics, quality of life (QoL) and user experience will be administered. Patient will rate itch and pain on a numeric rating scale (NRS). Non-invasive assessments including TEWL, skin hydration and skin erythema will be performed. Furthermore tape strips will be taken from the skin of the hands from the HCW. This implies that the stratum corneum, the uppermost dead layer of the skin will be

collected of the back of the hands using adhesive tapes, which is a minimally invasive procedure. This procedure has often been applied in the studies of our research group and elsewhere. Each visit will take approximately 15 minutes. The measurements are taken at the HCW*s workplace for their convenience.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

healthcare workers with prolonged wearing of occlusive disposable gloves

Exclusion criteria

not using disposable gloves during work

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	21-10-2024
Enrollment:	360
Type:	Anticipated

Medical products/devices used

Generic name:	disposable examination glove
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-11-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL87482.018.24