

efficacy of barrier cream with or without Honeyin intergtrigo

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Correcting the causative factors of intertrigo is critical. Take steps to eliminate friction, heat, and maceration by keeping folds cool and dry. The goals of pharmacotherapy for intertrigo are to reduce morbidity and to prevent complications. To...

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

Summary

ID

NL-OMON36225

Source

ToetsingOnline

Brief title

honey-barrier

Condition

- Epidermal and dermal conditions

Synonym

intertrigo

Research involving

Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W, Spring Medical
Driehoek 7 7312CN Apeldoorn

Intervention

Keyword: barrier creme, Honey, Intertrigo

Outcome measures

Primary outcome

The effect of a barrier cream with honey and zinc oxide ointment on reducing the irritative skin defects

Secondary outcome

Comfort of both treatments will be measured.

Study description

Background summary

Intertrigo is an inflammatory condition of skin folds, induced or aggravated by heat, moisture, maceration, friction, and lack of air circulation. Intertrigo frequently is worsened or colonized by infection, which most commonly is candidal but also may be bacterial, fungal, or viral. Intertrigo commonly affects the axilla, perineum, inframammary creases, and abdominal folds.^{1,2} Diaper dermatitis shows significant overlap with intertrigo. Intertrigo is a common complication of obesity and diabetes.

Pathophysiology Intertrigo develops from mechanical factors and secondary infection. Heat and maceration are central to the process. Opposing skin surfaces rub against each other, causing erosions that become inflamed. Sweat, feces, urine, and vaginal discharge may aggravate intertrigo in both adults and infants.

Frequency International Intertrigo is common, especially in hot humid environments. Intertrigo is a common complication of diabetes, and it affects most infants as a component of diaper dermatitis.

Mortality/Morbidity

As a complication of more serious disease, intertrigo should be considered a comorbidity. Intertrigo becomes most serious as a source of secondary infection.

Age

Intertrigo affects people who are very old and very young because of reduced immunity, immobilization, and incontinence.

Study objective

Correcting the causative factors of intertrigo is critical. Take steps to eliminate friction, heat, and maceration by keeping folds cool and dry. The goals of pharmacotherapy for intertrigo are to reduce morbidity and to prevent complications. To reduce friction and protect the skin the use of a barrier cream is often effective. Treatment of the superficial bacterial or mycologic infection is necessary. Honey works as an antiseptic with a broad-spectrum. We want to compare the therapeutic effect of a barrier cream with and without honey.

Study design

Single blind randomized study, zinc oxide ointment compared to barrier cream with honey in the treatment of intertrigo. We will be including 50 patients. Inclusion criteria are patients with intertrigo. Exclusion criteria those withdrawal of informed consent, with wounds and use of other barrier creams. The zinc oxide ointment and barrier cream with honey will be applied to the skinfolds. The effect of treatment (differences of skinfolds left-right) will be analyzed on day 7, 14 and 21.

Study burden and risks

Topical treatment with a barrier cream is a standard therapy. We hope that the barrier cream with honey will be easy to apply. And will be convenient for patients and staff use. Removal of barrier cream is not necessary, in contrast to the topical zinc oxide cream. This will lead often to inconvenience for patients and staff.

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

Patients with intertrigo

Exclusion criteria

Wounds and one sided intertrigo

Study design

Design

Study type: Observational non invasive

Masking: Single blinded (masking used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	30-06-2011
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MediHoney Barrier Cream
Generic name:	MediHoney Barrier Cream
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Zinc Oxide Ointment
Generic name:	Zinc Oxide Ointment
Registration:	Yes - NL intended use

Ethics review

Approved WMO	
Date:	22-04-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	
Date:	27-06-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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

EudraCT

CCMO

ID

EUCTR2011-001469-42-NL

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