Treatment of intertrigo with zinc oxide in ketoconazolecream with or without substitution of hydrocortisone-acetaat

Published: 12-03-2007
Last updated: 10-05-2024

Clinical trial to investigate a difference in effectiveness for the treatment of intertrigo in wich the combination of zinc oxide 10% in ketoconazole will to be compared with zinc oxide 10% and hydrocortisone-acetaat 1% in ketoconazole.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON30558

Source
ToetsingOnline

Brief title
Treatment of intertrigo with or without hydrocortisone?

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
intertigo, moist lesion

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: De kosten vallen geheel binnen de kosten van de reguliere gezondheidszorg

Intervention

Keyword: Hydrocortisone, intertrigo, Randomized Controled Trial, Therapy

Outcome measures

Primary outcome

Reduce in percentage of the area of the intertigo compared to the other side

that has not been treated with the hydrocortisone-acetaat.

Secondary outcome

Local complainments as pruritis, pain, redness and scaly. Also the results of

the cultured samples are evaluate whereby we will look at the percentage of

positive results and the reaction or the different treatments.

Study description

Background summary

Intertrigo is a skin disease especially seen in hospitals and other care-centers. This disease starts in the large skin folds as the groin, inframammary and in the axillae. There is no consensus for the treatment at this moment but the main point is to dry the skin. Of all the topical treatments, only the anti-myotics have an controled investigation.
In the Medical Center of Leeuwarden intertrigo is treatened with the combination of zinc oxide in ketoconazol or zinc oxide and hydrocortisone-acetaat in ketoconazole. Zinc oxide is to dry-in the skin, ketoconazole for the dermatofyt or yeast and hydrocortisone-acetaat for the redness and irritation of the skin.

Study objective

Clinical trial to investigate a difference in effectiveness for the treatment of intertrigo in wich the combination of zinc oxide 10% in ketoconazole will to be compared with zinc oxide 10% and hydrocortisone-acetaat 1% in ketoconazole.

Study design

It is a dubble-bline, randomized, standardtherapy-controled phase III study,

with a duration of aproximately 6 months. There is an minimum of 48 inclusions for the statistical calculations so there will be approximately 65 participants.

Intervention

All patients will have both the combination with substitution with hydrocortisone-acetaat as the cream combination without it.

Study burden and risks

There will be no extra burdening when a patient participate in our study because the study is therapeuticaly. Physical there may be a burdening because of the location of the intertrigo, wich are on the whole the intimate areas.
For the study it is necessary to have a good look at the intertrigo and trace it onto foil. This has to be done twice.
A sample has to be taken once, but this is a part of the normal care for the patients.
No invasive treatment is necessary in the interest of the study.

Contacts

Public
Medisch Centrum Leeuwarden

Henri Dunantweg 2
8934 AD Leeuwarden
Nederland
Scientific
Medisch Centrum Leeuwarden

Henri Dunantweg 2
8934 AD Leeuwarden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Two-sided intertrigo in the folds of the groin, axillairy or submammary
- The intertrigo may not been treated yet beside treatment with zincoxide.
- There has to be a control after 5-7 days.

Exclusion criteria

- Patients may not have a hypersensibility for one of the componements of the different creams
- Patients may not have a (skin)disease that might can influence the aspect or the threatment for this study neither have a contraindication to start the treatment.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2007
Enrollment:	65

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	hydrocortisone-acetaat
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	-
Generic name:	ketoconazole
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	-
Generic name:	Zinc oxide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-03-2007
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	26-03-2007
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
EudraCT	EUCTR2006-006234-18-NL
CCMO	NL15277.099.06