Effectiveness of local treatment for onychomycosis

Published: 26-08-2019
Last updated: 15-05-2024

To study the effect of local antifungal treatment of the toenails

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin appendage conditions
Study type	Interventional

Summary

ID

NL-OMON52904

Source
ToetsingOnline

Brief title
Local onychomycosis treatment

Condition

- Skin appendage conditions

Synonym
fungal infection of the nail

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Fonds Alledaagse Ziekten

Intervention

Keyword: amorolfine, miconazole, onychomycosis

Outcome measures

Primary outcome

Cure of the index nail after 26 weeks with miconazole or amorolfine compared

with non-active laque

Secondary outcome

- percentage of healing (percentage and onycho severity index)

- quality of life

- side-effects

- difference in effect between the three intervention groups

Study description

Background summary

Fungal infections of the toenails are frequently seen by patients and doctors.
It is unknown what the effectiveness is of local antifungal therapy.

Study objective

To study the effect of local antifungal treatment of the toenails

Study design

Randomised controlled clinical trial

Intervention

1) Miconazole laque, 2) Amorolfine laque, 3) Laque without antifungal effect (Byte-x).

Study burden and risks

The two active substances used for this trial are approved for sale on the European market for this indication. We do not expect any negative health effects of the interventions. The only side-effects known are local skin

irritation, which disappears after stopping the intervention. Participants are asked to fill in questionnaires three times during the study. We feel that the burden and risks associated with participation are ethically sound.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- age between 18 and 70
- onychomycosis of one to three townails (per foot)
- between 10% and 75% affected area of the nail
- matrix of the nail not involved
- no 'spikes' of the affected nail

Exclusion criteria

- pregnancy or breast feeding
- not able to give informed consent
- diabetes
- peripheral vascular disease
- malignancy
- mycosis of the whole foot
- allergy to components of the treatments
- use of vitamin K antagonists, oral glucose lowering medication, phenytoin.
- oral treatment with antifungal medications in the past half year

Study design

Design

Study phase:	4
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):	10-02-2020
Enrollment:	113
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Amorolfine
Generic name:	Loceryl
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	ByteX
Generic name:	ByteX
Product type:	Medicine
Brand name:	Miconazole
Generic name:	Daktarin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-08-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26092
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2019-000335-77-NL
CCMO	NL68851.058.19
OMON	NL-OMON26092

Study results

Date completed:	17-03-2023
Actual enrolment:	111