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

Public

Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2300RC NL

Scientific

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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