The Onycho Trial

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Local antimycotic treatment of fungal toenail infection is more effective than placebo

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fungal infectious disorders
Study type	Interventional

Summary

ID

NL-OMON26092

Source
Nationaal Trial Register

Brief title
Onycho trial

Condition

- Fungal infectious disorders

Synonym
Fungal nail infection; nail fungus; tinea unguium

Health condition

Onychomycosis

Research involving
Human

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Fonds Alledaagse Ziekten (FAZ)

Intervention

Explanation

Outcome measures

Primary outcome

Complete cure, consisting of both clinical and mycological cure of the index toenail at 6 months

Secondary outcome

Clinical improvement (defined as either ≤10% involvement of the index toenail or as ≥40% reduction)

Symptom burden as expressed by the ONYCHO questionnaire score

Quality of life based on the Short Form-12 survey

Adverse effects

Therapy compliance

Patient-perceived improvement

Treatment acceptability

Study description

Background summary

Fungal infection (onychomycosis) of the nails is a common ailment seen in GP practice, often found to be annoying and unsightly. In most cases it involves the greater toenail. The only clinically proven effective treatment is oral terbinafine or an imidazole for at least 3 months. GP's and dermatologists regard onychomycosis primarily as a cosmetic problem and not so much a medical one, therefore understandably being hesitant or reluctant to prescribe oral terbinafine. If treatment is chosen for more extensive forms of onychomycosis, oral therapy remains first choice however. With less severe, more limited forms of onychomycosis, local therapy might be a good alternative. If proven effective, this could lead to fewer prescriptions of oral terbinafine which is desirable given the rare but potentially serious side effects. A recent Cochrane Review states that more research into the effectiveness of local treatment is needed. Little research has been done into one of the most frequently used antimycotic

agents in the Netherlands, miconazole. Given the already proven effectiveness and potential side effects of terbinafine orally, this study focus is on comparing the two most commonly used topical agents (miconazole and amorolfine) versus placebo. The aim of this study is to investigate the effect of local treatment of onychomycosis of the toenail(s) with miconazole or amorolfine as compared to placebo.

Study objective

Local antimycotic treatment of fungal toenail infection is more effective than placebo

Study design

Total treatment and follow-up of 6 months

Intervention

Miconazole; Amorolfine

Contacts

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Eligibility criteria

Age

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

Inclusion criteria

1. Age 18 - 70 years

2. Onychomycosis of 1 up to a maximum of 3 nails per foot

3. Limited form of onychomycosis, defined as at least 10% and not more than 75% of the nail

(visually) affected

4. No involvement of the matrix

5. No spikes

Exclusion criteria

1. Known allergy or hypersensitivity for one of the study medications

2. Pregnancy or lactation

3. Presence of malignancy

4. Generalized fungal infection of the (rest of) the foot

5. Patients treated with oral antimycotic therapy within the last 6 months

6. Use of vitamin-K antagonists, oral antidiabetics and/or phenytoin

7. Peripheral arterial occlusive disease stages III and IV

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2020
Enrollment:	111
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

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

Study registrations

Followed up by the following (possibly more current) registration

ID: 52904
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8193
CCMO	NL68851.058.19
EudraCT	2019-000335-77
OMON	NL-OMON52904

Study results