

The efficacy of a nail laquer in daily practice use, in patients with persistent onychomycosis who failed a previous topical treatment

Submission date 14/01/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 10/07/2015	Condition category Infections and Infestations	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Onychomycosis is a common fungal infection of the nail mostly caused by dermatophytic fungi. Two compounds, amorolfine and ciclopirox, are currently used in a lacquer base as treatment. The study assesses whether treatment with Ciclopoli 8% Nagellack is useful in those patients (about 40-50%) who did not see any improvements after amorolfine local treatment.

Who can participate?

Approximately 70 patients with persistent onychomycosis, after unsuccessful topical treatment with amorolfine, have been included.

What does the study involve?

All participants that failed a treatment with amorolfine, received the same treatment with Ciclopoli® 8% Nagellack.

What are the possible benefits and risks of participating?

The study could offer the chance of healing those patients previously treated without success with amorolfine, with a response rate similar to the oral treatment but with lower drug exposure. As it is a topical administration, there are no risks.

Where is the study run from?

Ten dermatologists in Germany participated.

When is the study starting and how long is it expected to run for?

The patients were recruited between June 2011 and July 2012.

Who is funding the project?

Polichem SA (Switzerland).

Who is the main contact?
Francesco Scarci
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PM0921

Study information

Scientific Title
Ciclopoli® 8% Nagellack administration in onychomycotic patients who failed previously topical treatment

Study objectives
Onychomycosis is a fungal infection of the nail. It is the most common disease of the nails and constitutes about a half of all nail abnormalities. This condition may affect toenails or fingernails, but toenail infections are particularly common.

This observational study would highlight if a drug with an optimal nail penetration, such as the water-soluble 8% ciclopirox lacquer Ciclopoli® 8% Nagellack, is useful in the real life onychomycosis treatment, in those patients unable to convert to negative direct examination (KOH) after amorolfine local treatment as no controlled data on amorolfine negative conversion of KOH were available.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Bavarian Landesärztekammer [Ethik-Kommission der Bayerischen Landesärztekammer], 21/04/2011, ref: 7/11049

Primary study design

Observational

Study design

Observational study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Onychomycosis

Interventions

Observational study over a period of 24 weeks in patients unsuccessfully treated topically with a different antimycotic nail laquer.

According to the scientific information, the usual treatment duration is 6 months. Ciclopoli® 8% Nagellack should be applied once/day on the affected nails. Nevertheless, it is recommended to treat all nails, even if they are not affected. Therefore the period that the patients underwent to the treatment was 6 months with visits at 3 different timepoints (recruitment, 3 months and 6 months),

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

8% ciclopirox lacquer Ciclopoli® 8% Nagellack

Primary outcome(s)

Negative conversion of direct microscopy examination (KOH) of the target nail after 6 months of treatment

Key secondary outcome(s)

1. Clinical improvement of the target nail (change of affected area compared to baseline assessed by Physician) after 3 and 6 months of treatment
2. Clinical improvement of the other affected nails (change of affected area compared to baseline assessed by Physician) after 3 and 6 months of treatment
3. Clinical evaluation of the number of affected nails at baseline and at the end of 6-month therapy
4. Patient's treatment satisfaction assessed by Clinical Global Impression-scale (CGI), after 3 and 6 months
5. Investigator's treatment satisfaction assessed by Clinical Global Impressionscale (CGI) with the previous amorolfine treatment at Screening
6. Investigator's treatment satisfaction assessed by Clinical Global Impressionscale (CGI) after 6 months
7. The evaluation of safety

Completion date

31/12/2013

Eligibility

Key inclusion criteria

Patients with the following characteristics should be considered for inclusion into the study:

1. Diagnosis: distolateral or subungual mild to moderate onychomycosis (ICD 10, Ziffer B 35.1)
2. Patients of both gender, aged above 18 years old
3. Indication for local treatment of Onychomycosis with Ciclopoli® 8% Nagellack
4. Laboratory finding positive for fungi (KOH examination)
5. Affected area of minimum 10% of at least one toenail or one fingernail
6. Unsuccessful topical amorolfine treatment lasted at least 6 months and concluded no later than one month before inclusion
7. No concomitant oral treatment for onychomycosis
8. Signed informed consent form (ICF)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Onychomycotic patients with indication to oral treatment

Date of first enrolment

01/06/2011

Date of final enrolment

01/07/2012

Locations

Countries of recruitment

Germany

Study participating centre

Facharzt für Dermatologie Phlebologie Allergologie
Freiburg
Germany
79100

Sponsor information

Organisation

Polichem SA (Switzerland)

ROR

<https://ror.org/05735qy63>

Funder(s)

Funder type

Industry

Funder Name

Polichem SA (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration