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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

Registration date
23/01/2013

Overall study status
Completed

Last Edited
10/07/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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 Landesarytekammer [Ethik-Kommission der Bayerischen Landesarytekammer], 21/04/2011, ref: 7/11049

Study design

Observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Onychomycosis

Interventions
Observational study over a period of 24 weeks in patients unsuccesfully 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
Onychomychotic patients with indication to oral treament

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