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Clinical study to investigate the effectiveness of two medical devices in the treatment of onychomycosis (a fungal infection of the nails)

Submission date
16/03/2021

Recruitment status
No longer recruiting

Registration date
28/06/2021

Overall study status
Completed

Last Edited
24/07/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Onychomycosis is a fungal infection of the nails that causes discoloration, thickening, and separation from the nail bed.
This study will be conducted to evaluate the effectiveness of the Fungal Nail Treatment pen and the Fungal Nail 3-in-1 Treatment Solution in the treatment of onychomycosis based on the percentage of healthy nails. Furthermore, this study aims to evaluate the effectiveness of the Fungal Nail Treatment pen and the Fungal Nail 3-in-1 Treatment Solution in the treatment of onychomycosis based on the clinical cure (Clinical review / mycological cure of target nail), as well as clinical and patient evaluation in the improvement of nail appearance. Patient satisfaction and safety will be investigated.

Who can participate?
Adults aged 18 - 70 years, with mild-moderate onychomycosis affecting up to 60% of fingernails and/or toenails.

What does the study involve?
Study participation involves a screening session and multiple visits over a period of 6 months. Participants will be randomised to receive one of three registered therapies for the treatment of onychomycosis. Two of them are medical devices, the third is a pharmaceutical treatment.

What are the possible benefits and risks of participating?
Depending on the product efficacy, the potential benefit will be an improvement of the treated toenail or fingernail condition.
The sponsor has taken all the necessary measures to reduce the residual risk. However unexpected risks may appear. There may be a risk of local intolerance or allergic reaction following the application of the device as skin reactions.

Where is the study run from?
1. Medical Brands (Netherlands)
2. Eurofins Dermscan Pharmascan (Tunisia)

When is the study starting and how long is it expected to run for?
March 2021 to April 2022

Who is funding the study?
Medical Brands (Netherlands)

Who is the main contact?
Dr Guido van Amerongen, g.vanamerongen@medicalbrands.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
20E3241 / MB-FNV20-201

Study information

Scientific Title
Multicentric, randomized, comparative, evaluator blinded clinical study for the evaluation of efficacy and safety of two medical devices for the treatment of onychomycosis

Study objectives
The fungal nail treatments are effective at treating onychomycosis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/04/2021, Internal Ethics Bioethics Committee of Dermscan Tunisia (Avenue Tahar Ben Ammar E2, Centre Esthetical El Menzah 9 , El Menzah, 2092 Tunisie, Tunis, Tunisia; +216 50 877 399; contact@dermscan.com), ref: 20E3241

Primary study design
Interventional

Study design
Randomized parallel groups comparative multi centre single blind (for the evaluation of the primary endpoint)

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Onychomycosis (a fungal infection of the nails)

Interventions
Randomized study investigating the effects of two medical devices and Loceryl (positive control) for the treatment of fungal nail infections

Intervention group 1: Fungal Nail 3-in-1 Treatment Solution - Applied twice daily
Intervention group 2: Fungal Nail Treatment Pen - Applied twice daily
Comparator: Locéryl® (5% amorolfine) - Applied once/twice weekly

The treatments will be administered for a period of 6 months.

The device/product attribution will be performed using the randomization list edited before first patient randomization

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fungal Nail 3-in-1 Treatment Solution, Fungal Nail Treatment Pen, Locéryl® (5% amorolfine)

Primary outcome(s)
Percentage healthy nail determined by blind by digital analysis of photographs at day 180

Key secondary outcome(s)
1. Percentage healthy nail will be determined by blind by digital analysis of photographs on day 7, day 30 and day 90
2. Evaluation of microbiological efficacy of both treatments versus baseline and versus comparator by KOH staining and fungal culture on day 90 and day 180
3. Patient evaluation of efficacy using a diary at day 7, day 30, day 90, day 180

Completion date
01/04/2022

Eligibility

Key inclusion criteria
1. Patient having given freely her/his informed, written consent
2. Patient having a good general health

3. Age between 18 and 70 years
4. Patient with light to moderate distolateral subungual onychomycosis involving up to 60% of the affected great toenail or fingernail (after the nail has been trimmed). Each subgroup (toenail or fingernail) needs to represent at least 10% of each treatment arm
5. Patient with positive KOH staining
6. Patient cooperative and aware of the products modalities of use and the necessity and duration of the controls so that perfect adhesion to the protocol can be expected
7. Patient being psychologically able to understand information and to give their/his/her consent
8. Patient who agree to refrain from receiving pedicure/manicure, artificial nails and/or cosmetic nail varnish or other medication on the nail being treated for the entire study duration
9. Patient having stopped any systemic antifungal treatment since at least 6 months before screening and/or any topical antifungal treatment since at least 3 months before screening
10. Female of childbearing potential should use a contraceptive regimen recognized as effective since at least 4 weeks before screening visit and during the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
132

Key exclusion criteria
1. Pregnant, breastfeeding woman or woman planning a pregnancy during the study
2. Patient enrolled in another clinical trial or which exclusion period is not over
3. Patient with a condition or receiving a medication which, in the investigator’s judgment, put the patient at undue risk
4. Patient suffering from a severe or progressive disease (to investigator’s discretion) such as uncontrolled diabetes, peripheral circulatory disease, HIV, psoriasis, lichen planus, immunosuppressive pathology
5. Patient having a known allergy or hypersensitivity to one of the constituents of the tested products
6. Patient with cutaneous pathology on the studied zone (other than onychomycosis like angioma, dermatitis…)

Date of first enrolment
21/04/2021

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
Tunisia

Study participating centre
Eurofins Dermscan Pharmascan
39, Avenue Abou Loubeba El Ansari
El Menzah 7
Ariana
Tunisia
2091

Sponsor information

Organisation
Medical Brands

Funder(s)

Funder type
Industry

Funder Name
Medical Brands (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan
Participant level data will not be disclosed for confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Basic results	19/07/2024	No	No