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Investigating the treatment of fungal nail infections with a novel medical device

Submission date	Recruitment status	[_] Prospectively registered
27/07/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/02/2017	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/05/2021	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Fungal nail infections occur as a result of the fungi that cause athlete's foot infecting the nails. They cause the nail to become discoloured, thickened and distorted. This study is investigating a new medical device for the treatment of fungal nail infections. The device produces a gas plasma (similar to the plasma in a fluorescent light bulb) that kills the fungus under the nail. The aim of this study is to find out whether the device is capable of curing a fungal nail infection.

Who can participate?
Patients aged of 18 to 80 years with fungal nail infections in both large toenails

What does the study involve?
Samples are taken from both of the participant's toenails to confirm the infection. Participants are randomly allocated to one of four treatments with the medical device on one of their large toenails on one or two occasions. The treatment may take about an hour depending on the extent of the nail infection. Both toenails are observed for the following 12 months to check whether the infection has been cured and if new nail growth occurs. Nail samples and photographs of the toenails are taken after 1, 3, 6, 9 and 12 months. The treated toenail is compared to the untreated large toenail on the participant's other foot.

What are the possible benefits and risks of participating?
Fungal nail infections do not go away spontaneously and many sufferers have tried other treatments without success. Participating in the study may result in the successful treatment of their fungal nail infection. The device has been extensively tested and has been demonstrated to be safe to use on normal tissue and nail. If the device is targeted on one area of tissue then warmth will be noticed by the patient. The generated heat could become uncomfortable in some patients in which case the patient may move their foot away from the device. The main possible risk is that the patient receives a mild burn on their skin or nail.

Where is the study run from?
Adelaide Health Centre (UK)

When is the study starting and how long is it expected to run for?
August 2016 to July 2017

Who is funding the study?
BOC / Linde (UK)

Who is the main contact?
Dr David Voegeli

Contact information

Type(s)
Public

Contact name
Dr David Voegeli

Contact details
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PF4-001

Study information

Scientific Title
A randomised pilot clinical investigation of a novel plasma device (PF4) with concurrent controls in toenail onychomycosis

Acronym
CAPTOE

Study objectives
A gas plasma generated by a novel medical device is capable of curing a fungal nail infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee London Stanmore, 19/07/2016, ref: 16/LO/0671

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Patients are randomised to one of four different treatments with the novel device on the right or the left large toenail. The treated toenail is compared to the untreated control (the other large toenail in the same patient). The area of the nail to be treated comprises the visibly infected nail plus a margin of 5mm. The total area to be treated is divided into treatment 'spots' of 6mm x 6mm by placing a grid on the nail to determine the number of spots. The four treatment groups are:
1. Long continuous treatment on each spot followed by one short treatment under nail
2. Short treatment on each spot repeated 6 times followed by one short treatment under nail
3. Short treatment on each spot repeated 12 times followed by one short treatment under nail
3. Short treatment on each spot repeated 6 times followed by one short treatment under nail - whole process repeated 2 weeks later

Intervention Type
Device

Primary outcome measure
Measured at 1, 3, 6, 9 and 12 months after treatment:
1. Clear nail growth: measuring the distance of the visible infection from the lunula and comparing the measurement to the baseline measurement
2. Mycological cure: determined by laboratory tests (microscopy and culture of the nail samples)

Secondary outcome measures
Onychomycosis severity index (OSI). This is measured by the research podiatrist before treatment and at 1, 3, 6, 9 and 12 months. At each of these time points photographs of the nail are taken and an independent onychomycosis severity index will be given by an independent expert based on the photographs.

Overall study start date
29/07/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Participants who can provide informed consent
2. Male or female participants
3. Aged 18-80
4. Mycologically confirmed distal subungual onychomycosis in both hallux toenails with 25 – 75% involvement of the nail area

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Participants < 18 years old
2. Participants > 80 years old
3. Participants currently being treated for onychomycosis or who have been treated within the past four months using topical drug therapies
4. Participants who have taken oral antifungal agents or had laser treatments in the last 12 months
5. Participants who have been involved in other drug or medical device clinical trials in the past 3 months which may affect the safety or efficacy of this study
6. Participants with ulcerations around the toe nails
7. Participants with total dystrophic onychomycosis involving the lunula/nail matrix
8. Participants with peripheral vascular disease, immune-suppression, loss of sensation in either foot, or with any other medical state which warrants definitive antifungal therapy
9. Participants with <25% or >75% onychomycosis involvement of the nail area
10. No use of nail varnish on the toe nails for at least four weeks before the first treatment and for at least four months after the last treatment

11. Participants with proximal subungual onychomycosis
12. Participants with superficial white onychomycosis
13. Participants with psoriasis, lichen planus or other medical condition which has the ability to induce nail changes
14. Participants who cannot communicate competently in English
15. Women of childbearing potential who are, or might be, pregnant at the time of the study enrolment or who plan to become pregnant within three months of the study treatment
16. Participants with a pacemaker, implantable cardiac device, deep brain stimulator, gastric stimulator or any other electrically powered implantable device

Date of first enrolment
01/08/2016

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Adelaide Health Centre
Southampton
United Kingdom
SO16 4XE

Sponsor information

Organisation
Solent NHS Trust (UK)

Sponsor details
Western Community Hospital
William Macleod Way
Southampton
England
United Kingdom
SO16 4XE

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/04fsd0842

Funder(s)

Funder type
Industry

Funder Name
BOC / Linde (UK)

Results and Publications

Publication and dissemination plan
A publication is planned in a high-impact peer reviewed journal with the intent to publish by July 2019

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to UK data protection laws. The data will be held by the Sponsor.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No