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A study evaluating three treatments for foot callus

Submission date	Recruitment status
15/04/2015	No longer recruiting
Registration date	**Overall study status**
30/04/2015	Completed
Last Edited	**Condition category**
25/05/2016	Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Calluses are hard, rough areas of the skin most commonly found on the heel or the ball of the foot. They result from the skin continually being rubbed against something (such as a shoe). It is the most common foot skin complaint in people of all ages andmany seek advice and treatment from podiatrists. They are a common cause of foot pain and can make walking more difficult. Currently, the gold standard (best available) treatment for calluses is scalpel debridement (cutting away some of the thickened skin with a scalpel) and regular treatment with topical keratolytics; these are products applied on the affected skin containing salicylic acid which can help soften the top layer of skin so that it can be easily removed. The need for effective over-the-counter topical treatments are warranted, as regularly clinical treatments can prove costly. Caustic and acidic compounds such as potassium hydroxide and trichloracetic acid are commonly used in relatively low concentrations in facial chemical peel products. More recently these compounds have been used in greater concentrations in callus removal preparations. The little evidence that is available as whether these treatments work is based on the opinions of the users rather than on objective quantitative measures of skin properties. The measurement of the improvement of the skin of the foot after such treatments would strengthen confidence in the selection of appropriate and effective treatments. The aim of these study was to compare how well two different treatments, potassium hydroxide and trichloracetic acid, performed in removing calluses on the foot.

Who can participate?
Adults (aged at leat 18) with a callus that had not been treated for the past 6 weeks.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in group 1 (control group) had their calluses removed with a scalpel on the first day of the study. Those in group 2 had their calluses treated with a potassium hydroxide based foot lotion once a day for three weeks. Those in group 3 had their calluses treated with a trichloacetic acid based foot lotion for 4 days, followed by 4 days of no treatment, followed by 4 days of treatment etc for 3 weeks. The performance of the three treatments were then measured by looking at whether the calluses had disappeared, the degree of hydration, elasticity of the skin and skin texture.

What are the possible benefits and risks of participating?
There is no robust evidence supporting the positive effects of treatments for foot calluses. This study provides information about how well the treatments work in comparison to each other and to the gold standard of care. The knowledge generated from this study is directly applicable to the clinical setting, where practitioners will be able to advise their patients on the most appropriate treatment regime for their feet. Strict inclusion criteria were used, therefore the risks to the participants was low. No adverse events were reported and the participant 'drop out' rate was low.

Where is the study run from?
Podiatry Division, School of Health Sciences, University of Salford (UK)

When is the study starting and how long is it expected to run for?
September 2012 to November 2013

Who is funding the study?
Reckitt Benckiser (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial evaluating three treatments for plantar callus in healthy adults

Study objectives
The null hypothesis is that there is no difference in the clearance rates of calluses at 3 weeks post randomisation between the three treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Salford, College of Health and Social Care Research Ethics Committee, 25/02/2012, ref: HSCR12/55

Study design
Pragmatic open three-armed randomised controlled trial conducted in one centre

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Callus (or hard skin)

Interventions
1. Removal of calluses using a surgical blade on day 1 of the study
2. Removal of calluses using potassium hydroxide based foot lotion once weekly for 3 weeks
3. Removal of calluses using a trichloracetic acid based foot lotion for 4 consecutive days followed by 4 days of no treatment and then 4 days of treatment etc for 3 weeks

Intervention Type
Procedure/Surgery

Primary outcome measure
The most painful or the largest callus was selected as the index callus.
The primary outcome was complete clearance of the index callus at 3 weeks after randomisation as determined by assessment by a HCPC registered podiatrist. 'Clearance' of calluses was defined as the restoration of normal skin upon close inspection, with the return of normal dermatoglyphics to the treated skin.

Secondary outcome measures
1. Improvement in hydration, elasticity, skin surface texture and callus size at 7 days, 14 days and 21 days
2. Change in quality of life (QoL) before and 3 weeks after treatment
3. Satisfaction with treatment at 3 weeks

Overall study start date
24/09/2012

Completion date
25/11/2013

Eligibility

Key inclusion criteria
Participants were included if any of the following criteria applied:
1. They were aged 18 years and older
2. They had plantar callus
3. They had not been treated in the previous 6 weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
Participants were excluded if any of the following criteria applied:
1. They had any skin disorders affecting the foot such as infections (e.g. Athlete's foot), dermatitis, psoriasis, un-healed skin wounds, ulcers or blisters
2. They had a systematic disease including peripheral vascular disease or musculoskeletal disorders of the foot or ankle, rheumatoid arthritis or diabetes

3. They had allergies to any topical foot preparations with similar ingredients to those used in the trial treatments
4. They were unable to reach their feet to apply the products

Date of first enrolment
24/09/2012

Date of final enrolment
25/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Podiatry Division
School of Health Sciences
Centre for Health Sciences Research
Frederick Road Campus
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Sponsor information

Organisation
University of Salford (UK)

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Sponsor type
University/education

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Industry

Funder Name
Reckitt Benckiser (UK)

Results and Publications

Publication and dissemination plan
The main trial results and study protocol will form the basis of an academic paper in a peer reviewed journal. The outcomes of the trial will be presented as a conference paper.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/05/2016		Yes	No