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A study evaluating three treatments for cracked heel skin

Submission date	Recruitment status
15/04/2015	No longer recruiting
Registration date	**Overall study status**
30/04/2015	Completed
Last Edited	**Condition category**
27/11/2019	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
Cracked heel skin is a common foot skin condition. It is unsightly and can be painful. The visual appearance of dry, cracked heels regularly drives sufferers to seek treatment and advice. The gold standard (best available) treatment is the physical removal of the cracked skin followed by regularly applying appropriate topical preparations (moisturisers). An effective moisturiser is thought to be vital in successfully treating cracked heel skin. Urea is the most common active ingredient in most foot creams due to its moisturising actions. Although these creams contain varying concentrations of urea, current evidence suggests that a 25% urea cream may hydrate the skin faster than creams containing less urea. However, past studies have been small and have focussed largely on subjective measures (opinion). A study using a range of validated, objective, quantitative measures to assess the response of cracked heel skin to specific treatments would strengthen confidence in the identification of effective topical treatments. The aim of this study was to test the performance of two different types of over-the-counter cracked heel skin treatments: 25% urea based cream and a gel heel sock containing moisturiser. These were then compared with the current gold standard podiatry treatment for the condition.

Who can participate?
Adults (aged over 18) with cracked heel skin that had not been treated for the last 4 weeks.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in group 1 (control group) received the gold standard treatment, that is physical removal of the cracked skin followed by moisturising. Those in group 2 were treated with a urea based foot cream twice a day for 2 weeks. Those in group 3 were treated with a gel sock, which they wore overnight, every night for two weeks. The performance of the three treatments were then measured by looking at whether the cracked heel skin had healed, 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 on the quality of heel skin. 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. One participant was withdrawn from the study as the heel skin appeared to deteriorate after 1 week of gel sock use. No other adverse events were reported.

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

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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 cracked heel skin in healthy adults

Study objectives
The null hypothesis is that there is no difference in the clearance rates of heel fissures at 2 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

Health condition(s) or problem(s) studied
Heel fissures (or cracks)

Interventions
1. Removal of heel fissures using a surgical blade and/ or rotary file on day 1 of the study
2. Application of urea based foot cream twice daily for 2 weeks
3. Use of gel sock overnight, daily for 2 weeks

Intervention Type
Other

Primary outcome measure
The most painful or the largest fissure was selected as the index fissure.
The primary outcome was complete clearance of the index fissure at 2 weeks after randomisation as determined by assessment by a HCPC registered podiatrist. ‘Clearance’ of

fissures was defined as the restoration of normal skin upon close inspection, with the return of normal dermatoglyphics to the treated heel skin.

Secondary outcome measures
1. Improvement in hydration, elasticity, skin surface texture and fissure size at 3 days, 7 days and 14 days
2. Change in quality of life (QoL) before and 2 weeks after treatment
3. Satisfaction with treatment at 2 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 cracked heel skin with closed fissures
3. They had not been treated in the previous 4 weeks

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
93

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 (including open heel fissures), 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

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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	observational results	01/12/2015	27/11/2019	Yes	No