

# A study evaluating three treatments for cracked heel skin

<b>Submission date</b> 15/04/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/04/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/11/2019	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> 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?

Dr Farina Hashmi

F.Hashmi@salford.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Farina Hashmi

### Contact details

School of Health Sciences  
Centre for Health Sciences Research  
Office: P.O. 41  
Brian Blatchford building  
Frederick Road Campus  
University of Salford  
Salford  
Manchester  
United Kingdom  
M6 6PU  
0161 295 5314  
F.Hashmi@salford.ac.uk

## 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  
University of Salford  
Salford  
Manchester  
United Kingdom  
M6 6PU

## **Sponsor information**

**Organisation**

University of Salford

**Sponsor details**

School of Health Sciences  
Centre for Health Sciences Research  
Frederick Road Campus  
University of Salford  
Salford  
Manchester  
England  
United Kingdom  
M6 6PU

**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?
<a href="#">Results article</a>	observational results	01/12/2015	27/11/2019	Yes	No