ISRCTN13166839 https://doi.org/10.1186/ISRCTN13166839

The long-term effectiveness of 40% salicylic acid plasters on corns

Submission date	Recruitment status
09/12/2008	No longer recruiting
Registration date	**Overall study status**
16/01/2009	Completed
Last Edited	**Condition category**
16/12/2015	Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Wesley Vernon

Contact details
Podiatry Services
Jordanthorpe Health Centre
1 Dyche Close
Sheffield
United Kingdom
S8 8DJ
+44 (0)114 2371183
wesley.vernon@sheffieldpct.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol Version 3 - December 2008

Study information

Scientific Title
The long-term effectiveness of 40% salicylic acid plasters on corns: a prospective pragmatic parallel-group randomised controlled trial

Study objectives
Null hypothesis: there is no difference in clinical and patient-centred outcomes in treatment of corns between use of corn plasters and usual treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective pragmatic parallel-group randomised controlled trial with equal randomisation

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Corns occuring on the foot

Interventions
308 participants will be recruited, 154 in each arm. One arm will receive 40% salicylic acid corn plaster treatment, the other usual 'scalpel' treatment. All study participants will be asked to describe the amount of pain experienced from the lesion at each visit using a visual analogue scale (VAS), whether they are satisfied with the treatment they are receiving using a simple questionnaire with pre-coded responses, to complete the Foot Disability Questionnaire and the Euro Quality of Life (EQ5D) instrument. These will be completed at each 3-monthly appointment and administered by the independent podiatrist (rater).

Patients in the corn plaster arm will then have the area cleared and a plaster applied and advised to keep on until the next visit 5 - 7 days later. On return, the plaster is removed and if the corn is loose, removal can be facilitated with blunt dissection. The plaster will be re-applied if the corn

is still present and reviewed weekly for up to 4 weeks from initial treatment, with a plaster applied at each visit if the corn is still present.

The size of the corn (if still present) will be documented at 3-monthly intervals for up to 12 months after initial treatment by an independent podiatrist blind to the initial treatment allocation. If the corn has resolved, this will be checked at each visit and documented. Patients in the scalpel treatment arm will have the corn removed with a scalpel at the initial treatment and then reviewed at 3-monthly intervals for 12 months where the size of the corn with be recorded if still present, with removal of the corn carried out at each appointment if required.

Any dissatisfaction with either treatment or complications will be recorded at each visit. In the event of an adverse reaction (development of infection, or unbearable pain), subjects will be provided with the appropriate podiatry care to alleviate symptoms but follow-up data will still be collected unless the participant withdraws their consent. Anyone in the corn plaster group whose corn re-occurs after initial monthly corn plaster treatment will receive usual scalpel treatment at 3-monthly intervals and this data will be included in the analysis under the intention to treat principle.

Participating podiatrists will be asked to complete a short questionnaire to assess their view of the two treatments at the end of the study.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Salicylic acid

Primary outcome measure
Presence at 3 months post-randomisation of an unhealed or recurrent corn that requires further ongoing treatment.

Secondary outcome measures
1. Presence of unhealed or recurrent corns at 12 months
2. Mean Visual Analogue Scale (VAS) pain score at 3, 6, 9 and 12 months
3. Foot pain disability scores at 3, 6, 9 and 12 months
4. Cost-effectiveness of corn plaster compared with usual care
5. Podiatrist satisfaction with the two treatments at 12 months
6. Patient satisfaction at 3, 6, 9 and 12 months

Overall study start date
01/04/2009

Completion date
31/03/2012

Eligibility

Key inclusion criteria

1. Adult patients (male and female subjects aged 18 years and older) with corns
2. Patients who are willing to take part for the duration of the study
3. Patients who have the capacity to make an informed decision and give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
308

Key exclusion criteria
1. Diabetes
2. Impaired circulation (including peripheral vascular disease, ischaemia)
3. A history of foot ulceration
4. Rheumatoid arthritis
5. Taking oral steroid medication
6. Dermatological conditions
7. Allergies to zinc oxide plaster
8. Allergies to salicylic acid
9. Neuropathy
10. Completely unable to reach their feet
11. Callus only and no corns
12. Infected corns or neurovascular corns
13. Pregnant or breast feeding
14. Peanut or soya allergy

Date of first enrolment
01/04/2009

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Jordanthorpe Health Centre
Sheffield
United Kingdom
S8 8DJ

Sponsor information

Organisation
Sheffield Health and Social Research Consortium (UK)

Sponsor details
c/o Dr Robert Dixon
Fulwood House
Old Fulwood Road
Sheffield
United Kingdom
S10 3TH
+44 (0)114 2718804
robert.dixon@shsc.nhs.uk

Sponsor type
Government

Website
http://www.shsrc.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: 2008-005313-21)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/09/2013		Yes	No
Results article	results	08/12/2015		Yes	No