ISRCTN11683925 https://doi.org/10.1186/ISRCTN11683925

Healing the Sole: A research project to investigate the effectiveness and benefits of individual homoeopathic treatment and chiropody 'debridement' for adults with chronic verrucas

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/04/2016	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RDC01630

Study information

Scientific Title
Healing the Sole: A research project to investigate the effectiveness and benefits of individual homoeopathic treatment and chiropody 'debridement' for adults with chronic verrucas

Study objectives
The objective of this research project is to investigate whether 'individual' homeopathic treatment is effective (by effective we mean has the verruca been cured or reduced in size) and beneficial (by beneficial we mean do the people in the study 'feel better in themselves'), compared to using 'Debridement' (the removal of the superficial callous that forms on the surface of the verruca) to individual adult patients with chronic veruccae, within a busy inner-city, multi-cultural foot-health (chiropody) clinic. The study will further investigate the clinical significant findings from the previous nine months of the study, based at St Leonards (funded by the Blackie Foundation). Was the 75% overall improvement in patient's veruccae achieved in the pilot study, attributed to homeopathic remedies or the therapeutic effect of the consultation? Was this improvement due to a combination of 'self-selection' and the 'natural history' of the condition. To find answers to these questions is the reason why this larger randomised trial using the two 'Debridement' active and placebo groups is proposed. This study will aim to provide the NHS and other foot health departments with more data on the treatments of veruccae. Utilising the outcomes from the study, it is hoped that foot health departments may be able to offer a pain free, holistic and more cost effective treatment for verrucae.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Skin and connective tissue diseases: Viral wards

Interventions
Debridement vs homeopathic treatment

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The cure or decrease in size of the verrucae (via photographs from a special grid film camera)
2. The quality of life of the patient - do the patients feel better in themselves? (via SF36 life-style questionnaire)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/1999

Completion date
01/01/2003

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/1999

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. Leonard's Primary Health Centre
London
United Kingdom
NW5 2JU

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (UK)

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