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EVerT2: dry needling versus nonsurgical debridement for the treatment of verrucae

Submission date
10/03/2015

Recruitment status
No longer recruiting

Registration date
19/03/2015

Overall study status
Completed

Last Edited
10/11/2017

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Verrucae (or plantar warts) are extremely common. They usually develop on the soles of the feet. They are flat and white in appearance and often have a black dot in the centre. They can be painful if they are on a weight-bearing part of the foot. They are caused by the human papilloma virus (HPV). Although most verrucae will spontaneously disappear without treatment, many patients seek treatment because they have persisted for many years, can be unsightly, can be painful or have prevented them from doing sports and other activities. There are many different treatments available, including the needling procedure. This involves using a fine needle to puncture the verrucae multiple times under a local anaesthesia. The goal is to place infected cells into the dermis (second layer of skin), to stimulate an immune response to destroy the virus. To date there has only been one small trial testing to see if this treatment works and no health economic analysis has been undertaken. The aim of this study is to investigate the clinical and cost effectiveness of the Falknor needling procedure for the treatment of verrucae.

Who can participate?
Adults aged 18 or older with a verruca that is suitable for both scalpel debridement and dry needling

What does the study involve?
Participants are randomly allocated into one of two groups. For those in group 1, their verruca is treated with scalpel debridement. For those in group 2, their verruca is treated using a needling procedure. All participants are then followed up for the next 24 weeks to see whether their verruca has been successfully removed or reduced in size, if they experienced any pain after treatment and whether they satisfied with the treatment offered.

What are the possible benefits and risks of participating?
It is anticipated that both the treatments will help by either reducing the size of the verruca or healing it completely. There may also be a reduction in pain associated with the verruca. However, this cannot be guaranteed. The information obtained from this study may help to inform treatment in the future for people with verrucae.

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

When is the study starting and how long is it expected to run for?
March 2015 to November 2016

Who is funding the study?
University of Salford (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
EVerT2: dry needling versus nonsurgical debridement for the treatment of verrucae - a randomised controlled trial

Acronym
EVerT2

Study objectives
The null hypothesis is that there is no difference in the clearance rates of verrucae as assessed by a blinded independent assessor at 12 weeks post randomisation between the two treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Salford, College of Health and Social Care Research Ethics Committee, 25/02/2015, ref: HSCR15/24
2. University of York, Department of Health Sciences Research Governance Committee, 18/02/2015, ref: HSRGC/2014/98/B

Study design
Single-centre pragmatic open two-armed randomised controlled trial

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Plantar verrucae (or warts)

Interventions
Participants with verrucae will be randomised in a 1:1 ratio to:
1. Removal of callus over the plantar verruca and needling under local anaesthesia
2. Removal of callus over the plantar verruca without local anaesthesia

Intervention Type
Procedure/Surgery

Primary outcome measure
The participant's verruca will be called the index verruca. In the case of a patient having multiple verrucae, the most painful or the largest verruca will be selected as the index verruca.
The primary outcome will be complete clearance of the index verruca at 12 weeks after randomisation as determined by blinded assessment by a HCPC registered podiatrist working at the clinical site. 'Clearance' of verruca will be defined as the restoration of normal skin upon close inspection, with the return of normal dermatoglyphics to the treated area of skin, i.e., uninterrupted skin striae as assessed by the podiatrist.

Secondary outcome measures
1. Clearance of the index verruca at 24 weeks as assessed in the same way as the primary outcome
2. Complete clearance of all verrucae at 12 and 24 weeks as assessed in the same way as the primary outcome
3. Self-reported clearance of all verrucae at 12 and 24 weeks
4. Self-reported time to clearance of all verrucae
5. Recurrence of verrucae at 24 weeks
6. Number of verrucae remaining at 12 and 24 weeks
7. Change in size of the 'index' verruca at 12 and 24 weeks (digital photographs of the verrucae will be taken for analysis using an appropriate software package to measure the surface area of the verruca(e))
8. Level of pain at 12 and 24 weeks
9. Level of pain 24 hours after the treatment
10. Number of treatments
11. Satisfaction with treatment at 12 and 24 weeks

Overall study start date
25/03/2015

Completion date
25/11/2016

Eligibility

Key inclusion criteria

1. The participant has a verruca that, in the opinion of the health care professional, is suitable for both treatments: scalpel debridement and dry needling
2. They are aged 18 years and over

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
58

Key exclusion criteria
1. The participant, in the opinion of the health care professional, is not suitable for local anaesthesia
2. They are currently in a trial evaluating other treatments for their verruca
3. They have impaired healing e.g., due to diabetes, peripheral vascular disease or any other condition
4. They are immunosuppressed or are currently taking immunosuppressant drugs such as oral corticosteroids
5. They are unable or unwilling to give informed consent
6. They are currently on renal dialysis
7. They have peripheral neuropathy
8. The participant is pregnant

Date of first enrolment
24/03/2015

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Salford
Podiatry Division

School of Health and Social Care
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Sponsor information

Organisation
University of Salford

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Sponsor type
Not defined

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
University/education

Funder Name
University of Salford Manchester

Alternative Name(s)
University of Salford, University of Salford, Manchester, USM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. The main trial results and study protocol will form the basis of an academic paper in a peer reviewed journal on its completion
2. The protocol will be published separately during the trial period in a peer reviewed academic paper
3. The outcomes of the trial will be presented as a conference paper on completion of the trial

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?
Protocol article	protocol	24/11/2015		Yes	No
Results article	results	01/11/2017		Yes	No