

EverT2: dry needling versus nonsurgical debridement for the treatment of verrucae

Submission date 10/03/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/11/2017	Condition category Infections and Infestations	<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Salford

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Sponsor information

Organisation

University of Salford

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

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