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Cryotherapy versus salicylic acid for the treatment of verrucae

Submission date	Recruitment status	[_] Prospectively registered
07/12/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/07/2016	Infections and Infestations	

Plain English summary of protocol

Background and study aims:
There are many different ways to treat verrucae, but there is very little evidence to tell healthcare professionals which is the best treatment. This trial compared two widely used verruca treatments, salicylic acid and freezing with liquid nitrogen (cryotherapy) to see which one was the best treatment.

Who can participate?
Patients over the age of 12 years with a verruca which could be treated with salicylic acid and cryotherapy could take part in the trial.

What does the study involve?
Patients either treated their verruca at home every day with salicylic acid for eight weeks or went to a healthcare professional, who used a freezing agent to treat their verruca for a maximum of 4 treatments. Patients also filled in some questionnaires and went to the clinic after 12 weeks so that the healthcare professional could see if their verruca had gone.

What are the possible benefits and risks of participating?
We hoped that people taking part in the study would have their verruca cured, however this could not be guaranteed. The information we gained from this study will now help healthcare professionals decide which sort of treatment to use with their patients. As the two treatments are widely used, we did not expect there to be any additional risks compared to routine practice.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
October 2006 to June 2010

Who is funding the study?
Health Technology Assessment Programme (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
HTA 05/513/02

Study information

Scientific Title
Cryotherapy versus salicylic acid for the treatment of verrucae: a randomised controlled trial

Acronym
EVERT (Effective Verruca Treatments)

Study objectives
The primary objective is to compare the clinical effectiveness of cryotherapy versus salicylic acid for the treatment of verrucae. To do this, we will test the hypothesis that patients receiving cryotherapy using liquid nitrogen delivered by the health care professional will have better treatment of verrucae in terms of the complete clearance of all verrucae as observed on digital

photographs taken at baseline and 12 weeks and assessed by an independent health care professional (e.g. podiatrist, GP, practice nurse) compared to patients self-treating with 50% salicylic acid (Verrugon).

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0551302
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0014/51233/PRO-05-513-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
UK MREC approval, 26/10/2004, MREC ref: 04/MRE04/59

Study design
Pragmatic multi-centre two-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Verrucae (plantar warts)

Interventions
Patients will be randomised equally between the two arms: daily self-treatment by the patient with 50% salicylic acid (Verrugon®) or cryotherapy using liquid nitrogen delivered by the health care professional.

Participants will be randomised to either daily self-treatment by the patient with 50% salicylic acid (Verrugon) for a maximum of 8 weeks or cryotherapy using liquid nitrogen delivered by the health care professional for a maximum of 4 treatments.

Intervention Type
Mixed

Primary outcome measure
Complete clearance of all verrucae as observed on digital photographs taken at baseline and 12 weeks and assessed by an independent health care professional.

Secondary outcome measures
1. Self-reported clearance of verrucae at 6 months
2. Self-reported time to clearance of verrucae
3. Data will also be collected on side effects of treatment, pain intensity after treatment, use of painkillers, restrictions to lifestyle due to having verrucae, treatment details and patient satisfaction with treatment.

Overall study start date
01/10/2006

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Patients aged 12 years and over
2. With a verruca that in the opinion of the health care professional is suitable for treatment with either salicylic acid or cryotherapy

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
266

Key exclusion criteria
1. Patients are currently in a trial evaluating other treatments for their verruca
2. They have impaired healing e.g. due to diabetes, peripheral vascular disease or any other condition which means the patient has impaired healing
3. They are immunosuppressed, e.g. have agammaglobulinaemia, or are currently taking immunosuppressant drugs such as corticosteroids
4. They are unable to give informed consent
5. They are currently on renal dialysis
6. They have cold intolerance e.g. Raynaud's syndrome or cold urticaria
7. They have any of the following conditions: blood dyscrasias of unknown origin, cryoglobulinaemia, cryofibrinogenaemia, collagen and auto-immune disease

Date of first enrolment
01/10/2006

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
York
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	08/02/2010		Yes	No
Results article	results	07/06/2011		Yes	No
Results article	results	01/09/2011		Yes	No
Results article	results	12/11/2012		Yes	No
Results article	results	12/07/2016		Yes	No