THE UNIVERSITY of York

Local headed paper

DEPARTMENT OF HEALTH SCIENCES

A STUDY OF DIFFERENT TYPES OF TREATMENT FOR VERRUCAE

Information Sheet

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You are being invited to take part in a research study, which aims to find out the best way to treat verrucae. Before you decide if you would like to take part you will need to understand why the research is being done and what it will involve. We would be grateful if you would read the following information and discuss it with your family and friends if you wish. Please ask if there is anything that is unclear or if you need more information and take time to decide whether or not you would like to take part.

What is the purpose of this study?
Verrucae are a common, infectious and sometimes painful problem. Most verrucae will disappear spontaneously after 6 to 12 months without treatment. However, patients may seek treatment from a podiatrist/GP/other Health Care professional if their verruca is painful or because they are being prevented from doing sports. There are many different ways to treat verrucae but it is unclear which treatment is best. The purpose of this study is to compare two of those treatments, an acid paste which you can buy over the counter from a pharmacist and a freezing technique, which is currently used to treat verrucae within the Podiatry Department/GP practice/other clinic at (insert name of specific site). We want to find out which is the best treatment to cure verrucae and what you thought about the treatment. We are also interested to know how much the treatments costs.

Who is carrying out the research?
This is a joint research project between the Podiatry Department/GP clinic/other clinic at (insert name of specific site) and the York Trials Unit. Qualified HCP at the clinic led by (HCP name) will treat all the patients. Two researchers, (name of researchers) from the Trials Unit at York University will collect and analyse the data.

Who is funding the research?
The NHS Health Technology Assessment Programme is paying for the research.

Why have I been chosen?
We are inviting all patients attending the Podiatry Department at GP practice/other clinic (insert name of specific site) who have a verruca to participate in this study. We hope to study 266 patients in total.

Do I have to take part?
It is completely up to you if you would like to take part. If you do decide to take part you will need to sign the consent form. For patients under the age of 16 a parent or guardian will be asked to sign as well. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?
If you wish to take part you will need to complete the questionnaire and consent form and take it with you when you attend the podiatrist/GP/ practice nurse/other health care professional for your first appointment. Because we do not know which of the two treatments is best we need to make comparisons by putting patients into two different groups. Which group you are put in depends on chance and is rather like tossing a coin. You will have a 50:50 chance of getting either treatment. Patients will have been sent an appointment by the podiatry clinic to have their verruca treated along with this information. All patients will be seen by the podiatrist/ GP/practice nurse/other health care professional at their first appointment. Those assigned to the salicylic acid paste treatment will be shown how to apply it. You will then be asked to take the treatment home with you and apply it daily up to a maximum of 8 weeks. We will also ask you to attend a further appointment in two week's time. Those assigned to the cryotherapy group will be required to attend follow-up appointments as required when the verruca will be re-treated if necessary depending on your verruca. At 12 weeks after the first treatment, all patients will be asked to attend for a final assessment of whether their verruca has been cured, even if their verruca has been cured before this time. We will take a photograph of your verruca at the start of the study and then regularly to see if your verruca is reducing in size. In this study it is important that the podiatrist carrying out this assessment remains unaware of the treatment you have received. We will therefore ask you not to mention or talk about the treatments you have received during the trial to the person carrying out this assessment. In order to help cover your travel costs to take part in this trial, we will reimburse you £5/£10 for each visit up to the 12 week visit you make for treatment for your verruca and £20 for the 12 week visit. You will also be sent four further questionnaires by the University of York at 1, 3, 12 and 24 weeks after you agreed to take part in the study. You can choose to complete either paper or on-line versions of these questionnaires. If after 12 weeks your verruca has not cleared up at this stage, the podiatrist will advise you of the best course of action, which may include further treatment.

What do the two types of treatment involve?
The first treatment involves the application of an over the counter preparation of a salicylic acid paste to the verruca. The podiatrist/GP/nurse/other healthcare professional will show you how to apply the paste at your first appointment. You will then be given the treatment to take home with you and asked to apply it daily up to a maximum of 8 weeks. The second option is the application of liquid nitrogen to the verruca tissue for ten to twenty seconds each treatment, and again this will be repeated every two weeks for a maximum of four treatments. The area will be padded after treatment and you will be advised how to care for the foot after treatment.

What are the side effects of any treatment received when taking part?
Occasionally, people report mild discomfort either during or after treatment. If this happens then report it to the podiatrist who will advise you how best to deal with this. If you become in any way concerned then contact (name of podiatrist/ GP practice nurse/other health care professional, Podiatrist/GP/practice nurse/other type of health care professional on tel (insert telephone number).

What are the possible benefits of taking part?
We hope that both the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with verrucae better.

What happens when the research study stops?
You will still receive treatment after the study has stopped, if this is necessary. The podiatrist will consult with you on the best course of action.

What if something goes wrong?
If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the University of York Trial's Unit complaints mechanisms will be available to you, alternatively the normal National Health Service complaints mechanisms may be available to you.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential, both at the clinic where you receive treatment and at the University of York. This will be in accordance with the Data Protection Act 1998. Your General Practitioner will be notified that you are taking part in the study. Study information must be made available to the Medicines and Healthcare Products Regulatory Agency, which supervises drug trials in the UK, and the relevant ethics committees in the UK. Representatives of these bodies may also examine your hospital or clinical records and, by signing the consent form, you are giving permission for these records to be examined. These organisations have strict policies regarding confidentiality. No records bearing your name will leave the hospital/clinic where you take part in the study. Your study data, that will be transmitted to the York Trials Unit for analysis, will be identified by a Patient ID Number only.

What will happen to the results of the research study?
All the participants in the study will be personally informed about the results once the study is completed. It is intended to publish the results in approximately Autumn 2010 in a suitable medical journal. If participants wish to obtain a copy of the published results they should contact the podiatry clinic for details. Individual participants will not be identified in any publication.

What do I do if I don't want to take part in this study?
No problem, when you attend the clinic to see the podiatrist your treatment will not be affected by this. However, even if you do not want to take part in our study we would very much like you to fill in the questionnaire and return it to the podiatrist when you attend for

treatment because we would like to know about the health of all people with verrucae. (You do not have to give personal details if you would prefer not to).

Who has reviewed the study?
This study has been reviewed and approved by Trent Multi Research Ethics Committee. All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by a NHS Research Ethics Committee before it goes ahead. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the Committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision to take part or not.

What do I do if I do want to take part in this study?
If you are interested in taking part please complete the enclosed questionnaire and sign the consent form, returning it to the podiatrist when you attend for your first appointment.

Where can I get further information about the study?
If you require any further help or information please do not hesitate to contact either (Podiatrist/GP/practice nurse/other health care professional name) the podiatrist/GP/practice nurse/other health care professional telephone number) or researcher's contact details.

What if I have any concerns?
If you have any concerns or other questions about this study or the way it has been carried out, you should contact the investigator [name etc], or you may contact the hospital/PCT [name etc] complaints department or the trial coordinator (name of trial coordinator).

THANK YOU FOR TAKING THE TIME TO READ ABOUT THIS STUDY

https://www.hsytu.york.ac.uk/verruca/login.aspx

https://www.verrucatrial.co.uk