PATIENT INFORMATION SHEET

TO BE PRINTED ON TRUST HEADED PAPER

The Effect of Using Copper Heelers in Alleviating Joint and Musculoskeletal Aches and Pains

Version 4 - 23 February 2010

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and if you have any queries, please discuss them with friends, relatives, hospital doctors or your GP if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Joint and muscle aches and pains are very common and widespread symptoms amongst the population. It is estimated that more than 2 million adults in the UK have varying degrees of osteoarthritis and/or rheumatoid arthritis causing such symptoms.

Alternative therapy has been used for a very long time to try and help these symptoms, such as the use of metal bracelets. One of the favourites of these metal bracelets is copper but other metals including silver and platinum are also used. Users have reported a varying degree of benefits.

Currently on the market, there are insoles that can go into the shoe which are made of copper, called copper heelers, and users have reported that they appear to have the same effect as the bracelets. We would like to properly test the claims made by users to see if the copper heelers reduce the symptoms of joint and muscle aches and pains.

Why have I been chosen?

You have been invited to take part because this study is looking at patients like you aged between 16 and 80 years old, male or female, and suffer with arthritic or musculoskeletal aches and pains requiring painkillers and/or anti inflammatory medicine.

Do I have to take part?

No. It is up to you to decide whether or not you would like to take part in the study. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw (come out of the study) 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 if I take part?

If you decide you wish to take part, your doctor or nurse will review your medical records and ask you some questions to ensure you fit the full criteria for entry into the study. You will then sign a consent form stating you wish to take part.

Because we do not know whether the copper really does have an effect on alleviating symptoms or if it is a placebo effect, we need to compare a) the copper heeler with b) a dummy (placebo) heeler. There will be equal numbers of patients in group a) and in group b). The decision as to whether you receive the copper heeler or the dummy heeler will be made randomly by a concealed envelope system. There will be an equal number of copper heeler and dummy heeler cards placed in envelopes and an independent person (who will have no information about you as an individual) will pick an envelope for you. You have an equal chance of being given either treatment group. You and your doctor will not be able to tell whether you receive the copper or the dummy heeler as they will look and feel identical to each other. You will also be asked to refrain from wearing a copper bracelet for the full duration of the trial (12 weeks).

We will provide you with a heeler (insole) fitted with self adhesive material which you can fit to your footwear. It is best that you use these heelers continuously for the period of the trial. The heelers can be worn with any footwear including trainers, golf shoes and your normal shoes etc. You can wear your socks and tights normally. The heelers will come in different sizes to fit your shoe size and you can be provided with two pairs. The heelers are fitted with an adhesive material which can easily be fixed to the footwear. The heelers need to be worn as long as possible during the day: eight hours is recommended. Should you spend a significant amount of time not using the heelers (for example, due to illness or other personal reasons), please advise the nurse who will make attempts to postpone the following assessment session for a commensurate amount of time. If you anticipate the postponement might continue for longer than one week, please let the nurse know.

You will be assessed initially before the trial, and if included in the trial and provided with the heelers, further assessment will be carried out every 2 weeks for a period of 8 weeks and then a final visit at 12 weeks. Therefore you will be required to visit the hospital a total of 6 visits over 3 months. The assessment will be carried out on a one-to-one basis, and will include pain score (visual analogue scale on paper), functional score and the frequency of the dose of the medication you were using. You will not be subjected to any investigation in the way of blood tests, x-rays or any other investigative procedures. We will also ask you to complete a questionnaire for some of the visits to assess if the heelers are having any effect on your daily activities. You must inform your doctor if your symptoms get worse or if you notice any other effects from using the heelers. If you are allergic to copper or any other metal, we advise you not to take part in the study. If you are pregnant or undergoing pre-conception planning interventions, we advise you not to take part in the study.

What are the benefits of taking part in this study?

Many users have reported some relief of their arthritic and musculoskeletal aches and pains and even improvement in their mobility with the use of the copper heelers. However, this has not been clinically proven. In this trial we need to scientifically assess the beneficial effect of these heelers. All information gained from this trial will tell us more about the use of copper in reducing the symptoms of joint and muscle aches and pains, which may benefit other patients in the future.

What are the disadvantages of taking part?

We do not believe there are any major disadvantages or risks to taking part.

There is the chance that you will receive the dummy heeler, but this may still have a positive effect on your symptoms. You will still be able to take your current treatments and nothing will be withheld.

Sometimes the heelers can leave a green residue on your feet. This can be easily washed off with warm soapy water. There are no other adverse effects to be expected from using these heelers. It is commonly known that some metals can cause green or black staining on the skin, for example, copper, nickel and silver may all result in some level of staining, and yet it may also depend on an individual's body chemistry, some of whom may be more prone to staining than others. In this regard, study participants whose skin does show signs of staining will not be aware as to the exact metal which is the cause.

Unfortunately, there is no additional funding within the budget to allow for reimbursement specifically to study participants. However, those who receive state benefits will be able to apply for reimbursement at the hospital in the usual manner. To apply for such reimbursements, you will need to retain your travel receipts and surrender them at the time of requesting reimbursement. The Research Nurse dealing directly with you in the clinical setting will be able to provide advice on this process.

What if something goes wrong?

Things can go wrong in hospital just as in any other part of life but this happens very rarely. If you feel that your treatment in hospital has not been right or has harmed you in some way, you may ask the hospital to make amends. If you take part in this study, the usual compensation systems which apply to all patients in all hospitals in England will still apply to you. You do <u>not</u> lose any rights by being in this research. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints system will 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 study will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

There is no need to inform GPs that their patients are taking part in the study.

What will happen to the results of the research study?

We hope that the results of the study will be accepted to be published in about 6-12 months time as it takes time to analyse the results. We will send you a copy of the results if you wish at that time. You will not be identified in any report/publication.

Who is organising and funding the study?

This study is being run by Researchers at the University of Wolverhampton who will also act as Sponsor for the research. The research is being conducted in collaboration with the Research and Development Directorate at New Cross Hospital. Funding support has provided by the company providing the copper heelers, Master Shoe Makers, 12 New Cavendish Street, W1G 8UN.

The South Staffordshire Local Research Ethics Committee and the School of Health and Wellbeing at the University of Wolverhampton have independently reviewed and approved this study.

Who should I contact for further information?

Whenever you want to get more information about this study or in an emergency please contact:

Dr Angela Morgan, Senior Researcher,
University of Wolverhampton,
Tel: 01902 322455
Or
Research Nurse,
Telephone number: 01902 695065
Research & Development Directorate, New Cross Hospital, Wolverhampton

If you have any concerns or complaints, then please contact:

Name Yvonne Hague, Research & Development Directorate Manager
Address Research & Development Directorate, McHale Building, New Cross Hospital
Telephone number 01902 695065

If you wish to seek some independent advice then please contact:

Name Lorraine Evans, Research & Development Project Manager
Address Research & Development Directorate, McHale Building, New Cross Hospital
Telephone number 01902 695065

Thank you for taking the time to read this information.