Queen Mary University of London

Barts and The London NHS NHS Trust

Version 2 29th March 2011

'Participant Information Sheet'

Part 1

1 Study title:
Assessment of the Effectiveness of Extracorporeal Shock Wave Therapy (ESWT) for Soft Tissue Injuries (ASSERT)

2 Invitation paragraph
We would like to invite you to take part in our research study. Before you decide we would like you to understand why the study is being done and what it would involve for you. Your clinician will go through the information sheet with you and answer any questions you have. We'd suggest this should take about ten minutes. Please take time to read the following information carefully. (Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study). Talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3 What is the purpose of the study and why have I been invited to take part?
Extracorporeal shockwave therapy has been shown to be effective in the treatment of a number of chronic conditions including tendon disease in the elbow, shoulder, and pain under the heel. When conservative therapy has not been effective in relieving pain and other symptoms, extracorporeal shock-wave therapy (ESWT) has been used giving results such as relief of pain and improved function that are sometimes as good as those achieved by means of surgical procedures. You will already have discussed with your clinician what treatment option is best for you with ESWT being the desired treatment option. This will not be affected and is standard clinical care. The element that you are choosing is the development of a database. We have developed a database which will enable data to be entered in a systematic way to enable the evaluation of this treatment to be undertaken in a scientific and systematic manner so as to inform future practice.

At present ESWT is only used in a few settings with the effectiveness of the treatment being monitored in a non-consistent manner. However, there is no UK database which monitors the effectiveness of the treatment in a formal manner as recommended by The National Institute of Clinical Excellence (NICE).

The results of the research will be published and you will be able to receive a copy of the results if requested. You will not be identifiable in any report or publication as your details will remain anonymised.

4 Do I have to take part?
No. Whether or not to join the study is up to you. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, 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.

5 What will happen to me if I take part?
If you decide to take part in the study you are therefore giving permission for data about your treatment and recovery to be included on a UK database. As is usual practice you will be asked to complete a couple of questionnaires about your treatment and recovery following EWST. This information will be entered by your clinician onto a UK database. All the information on the database will be analysed at a later date to help to tell us how patients recover following ESWT. However, these future studies will be given separate ethical approval in their own right.

The data will be collected over 2 years and you will be asked to complete the same questionnaires at initial entry into the study (baseline), 3 months, 6 months, 12 and 24 months following treatment at the same time as when you will be seen by the consultant or via email or telephone if you do not require to see the Consultant. No extra journeys will be required.

6 Expenses and payments?
No expenses will be offered as the study does not require any extra visits to the hospital.

7 What will I have to do?
Being involved in the study would mean at study entry, 3, 6 12 and 24 months following treatment you will be asked to fill out some questionnaires about your treatment and recovery following ESWT. Your doctor will enter the details onto a UK database to monitor the overall effectiveness of ESWT treatment.

8 What are the alternatives for diagnosis or treatment?
This study involves the collection of information about ESWT treatment and recovery in a formal database to monitor in a scientific and systematic manner the effectiveness of a treatment that has already been decided upon prior to informing you of this study. All alternatives will have been discussed with the specialist doctor and this study is asking for consent to record the data on the effectiveness of the treatment that has already been decided upon.

9 What are the other possible risks of taking part?
We cannot foresee any risks in taking part in the study as it involves adding recovery information to a database to be analysed in a systematic and scientific way.

10 What are the side effects of any treatment received when taking part?
The side effects of the shock wave therapy will have been explained to you by your consultant. There are no side effects in being involved in this study as it involves the consent for your details and recovery following the treatment to be recorded on a database.

11 What are the possible benefits of taking part?
We cannot promise the study will help you but the information we get might help improve the treatment for people receiving shock wave therapy.

12 What happens when the research study stops?
Following completion of the study the data obtained on the database will be analysed to review the effectiveness of the shock wave therapy. All participants will be informed of the results of the study if they express an interest. All results will be disseminated widely.

13 What happens if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

14 Will my taking part in this study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

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Part 2

1. What if relevant new information becomes available?
If the study is stopped for any reason, we will tell you and arrange your continuing care.

2. What will happen if I don't want to carry on with the study?
You are free to withdraw at any time, 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. If you withdraw from the study, we will stop any future data collection, but we will need to use the unidentified data collected up to your withdrawal.

3 What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [contact number: Professor Maffulli/Gayle Maffulli (Trials Manager) 020 8223 8839]. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone 020 7377 6335, minicom 020 7943 1350, you can also visit PALS by asking at any hospital reception.
If you want to make a formal complaint please contact: Jarrard O'Brien, Quality Development, Barts and The London NHS Trust, Healthcare Governance Directorate, 3rd Floor, Prescot Street. Tel: 020 7480 4857.

Harm
Queen Mary University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

4 Will my taking part in this study be kept confidential?
Your confidentiality will be safeguarded during and after the study by:

Policy to ensure anonymity
To ensure the data collected on you remains anonymous your consultant will be given a unique centre number which will be used to log into the secure database. You will be given a study number which will be used when entering all the data

about you, your treatment and recovery following ESWT. Any data which may identify you will be held on secure servers managed by a secure database company (twentytwoseven). The only person who will have access to this information is Professor Maffulli (the lead Consultant for this study).
By consenting to be involved in this study you give the research team permission to access your information. All information collected about you during the course of the study and after completion will be kept strictly confidential and all of the research team will abide by the Data Protection Act 1998 and the rights you have under this Act.

5 Involvement of the General Practitioner/Family doctor (GP)
Your GP may be notified of your participation in the trial, with your consent.

6 What will happen to the results of the study?
The results of the study will be published in peer reviewed journals, presented at Conferences and help to inform future practice. You can request to have a copy of the published results if you let a member of the research team know that this is your wish.

7 Who is organising and funding the research and where was it reviewed?
This study is being funded by Spectrum Technology and IMPACT QM (Queen Mary University of London) funding stream. The funding covers the time for the researchers to set up and run the study. No additional payments will be made to Consultants or staff.

8 Who has reviewed the study?
All research in the NHS (private sector) is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by South East Research Ethics Committee.

9 Further information and contact details:
If you would like further information on:

General information about research and whether to participate:
Research and Development Office
Barts and the London NHS Trust
Queen Mary's Innovation Centre
Lower Ground Floor
5, Walden Street
London
E1 2EF
Reception tel: 020 7882 7250

Specific information about this project:

Professor Nicola Maffulli (Lead for the study and Professor of Sports and Exercise Medicine/Orthopaedic Consultant)
Mrs Gayle Maffulli (Trials Manager/Research Nurse)
Dr Stephanie Hemmings (Clinical Lecturer/Research Fellow)
Centre for Sports and Exercise Medicine
Queen Mary University of London
Bancroft Road
Mile End
London
E1 4DG
Tel: 020 8223 8839

Who to contact if unhappy:

Advisory Liaison Service (PALS) 020 7377 6335, minicom 020 7943 1350, you can also visit PALS by asking at any hospital reception.