**{insert local letterhead}**

**(MAPP) Multiple Myeloma: Associated Back Pain Prevention Study**

**A Comparison of Early Interventional Treatment**

**for Associated Back Pain Prevention Study**

**Principal Investigator**: **Mr Sandeep Konduru** Consultant in Trauma and Orthopaedic Spinal Surgery, University Hospitals of North Midlands NHS Trust, Royal Stoke University Hospital, Newcastle Road, Stoke-on-Trent, Staffordshire, ST4 6QG

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**PATIENT INFORMATION SHEET**

We would like to invite you to participate in a research study. Before you decide whether to participate or not, it is important for you to understand why this research is being done and what it will involve. Please take the time to read the following information carefully and decide whether or not you wish to take part. One of the study team will be available to go through it with you and answer any questions you may have.

1. **What is the purpose of this study?**

Multiple Myeloma is a type of blood cancer that can result in fractures. This is problematic if the fractures occur in the spine. If left untreated the fractures can lead to severe back pain, spinal collapse and eventual spinal deformity. The routine treatment for this back pain is pain medication and surgery to correct the spinal problem. There is some evidence that using an external back brace can help reduce the intensity of back pain and prevent spinal deformity in patients with myeloma. But, using a back brace may be restrictive and we do not know the long term benefit of using one.

The aim of this study is to answer a series of questions that will help us to decide if it is possible to run a larger full-scale trial. The large trial will help us answer the question as to whether the back brace decreases back pain and spine-related disability in patients with multiple myeloma.

1. **What device or procedure is being tested?**

We will test a spinal back brace as an early treatment for the relief of back pain and prevention of further spinal deformity in multiple myeloma patients. A spinal brace is a commonly used device which offers support and stability for the spine. The brace spans from the upper chest to the waist. They are fitted by trained specialists called orthotists.

1. **Why have I been invited to take part?**

You have been chosen because you are over 18 years of age and been diagnosed with multiple myeloma with spinal involvement causing back pain. You will be one of several patients that will be invited to this study to answer the questions as to the best way to manage this type of associated back pain.

1. **Do I have to take part?**

It is up to you to decide whether or not to take part. We will describe the study and go through the information sheet with you. If you agree to take part you will be asked to sign a consent form. A copy of your consent form will be sent in a secured envelope to the study coordinating centre at University Hospital of North Midlands NHS Trust. This will be kept separately to your study data.

If you agree to take part and then change your mind you are free to withdraw at any time without giving a reason. This will not affect your treatment or the standard of care you will receive. If you do not wish to take part, we will give you the option to complete a questionnaire to let us know the reasons why you declined the study. This information will help us when designing our future study.

1. **What will happen to me if I take part?**

If you agree to participate in this study you will be given time to read through this information sheet and ask as many questions as you like to the research team to ensure you understand the trial and your treatment.

Participation in the study will not affect your routine treatment for multiple myeloma.

If you decide to join the trial, you will have a routine MRI scan of the whole spine and plain X-rays of the spine.

This information will be checked to ensure you meet the criteria for the study. If, after this information is reviewed, you do not meet the criteria, you will not be able to take part in the study and will follow the standard treatment pathway outside of the study. This will not affect your treatment or the standard or care you will receive.

If you meet the criteria you will be randomly allocated to either have routine treatment with a brace or without a brace. You will have a 50:50 chance of receiving either treatment. You will also be asked to complete a number of questionnaires and we will collect some information about you and your medical history.

If you are allocated to receive a brace, you will be measured and fitted for one by the orthotist. You will need to wear this throughout the day (except whilst in bed) for 3 months. The brace will fit over a vest under your clothes.

All patients:

Six weeks after joining the study you will return to the outpatient clinic for a routine clinical assessment. You will also be asked to complete a number of questionnaires for this trial at this appointment.

Three months after joining the study you will again return to the outpatient clinic for a routine clinical assessment, an MRI scan of the whole spine and plain spine X-rays. You will also be asked to complete a number of questionnaires and the spinal brace will be removed if you had one fitted for the trial.

At both of these follow up appointments we will also collect information about you including details of any treatment or imaging you have had, and any medication you have taken. If you have been allocated to receive the brace, we will collect information about when the brace was fitted and any adjustments you have had or any visits to the orthotist.

You will also be asked to complete a questionnaire in which you will be asked your thoughts on your experiences while in the study.

If you agree, you may also be asked to take part in an interview with one of our researchers, who works for Keele University to go through your responses in more detail. This interview is optional, you do not have to take part. This may be face to face or by telephone. This interview call may be recorded.

You may receive any treatment such as radiotherapy or surgery as per standard care regardless of whether you have a brace or not.

Three months after you have finished taking part in the study the research team will look at your medical notes and record any surgeries you may have had.

1. **Expenses and Payments**

For participation in this trial you will not be required to attend any extra outpatient clinic visit in addition to those considered routine for your treatment, as such there are no expenses or payments provided by this study.

1. **What are the possible risks or disadvantages of taking part?**

When you have your spinal X-ray at 3 months you will be briefly exposed to radiation. The amount of exposure you will have from a Spinal X-Ray is equivalent to the background radiation you would be exposed to in the UK in a few months to 2 years in everyday life. The X-ray is standard care so there is no additional risk above what you would receive if you did not take part in this study.

Possible risks of wearing a brace may include some skin irritation and potential restriction during prolonged sitting or driving. You will have access to an orthotist throughout the study if you have any problems.

There are no additional risks involved in taking part in this study as all the available treatment options are considered routine clinical practice and performed ordinarily to treat this condition within your hospital.

1. **What are the possible benefits of taking part?**

Some potential benefits of having a brace may be prevention of pain and spinal collapse and reducing the need for further surgery or prescribed pain killers. However, even if you do not receive the brace, you will receive continuous supervision of your pain and disability levels while in the study.

1. **What happens when the research stops?**

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identifiable in any reports or publications resulting from this study. If you would like, we can send you a trial summary at the end of the study.

1. **What if there is a problem?**

If you have any safety concerns, during the study please contact the local research team in the first instance on: (insert local research team contact details).

If you have a complaint about any aspect of this study or its staff, you can contact the local Patient Advice and Liaison Service (PALS) on {insert local PALS details}.

If you wish to complain formally, you can do this through the NHS Complaints Procedure at University Hospitals of North Midlands NHS Trust.

You can also find further information on ethics in research on the National Research Ethics Service website ([www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk)).

The NHS indemnity operates in respect of the clinical treatment with which you are provided. In the unlikely event of harm during this research study due to someone’s negligence, then you may have grounds for legal action for compensation against the Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

1. **Will my taking part be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. A copy of your contact details and signed consent form will be sent to the study organisers but all other information will be anonymised with a unique study number. No electronic version of the consent form will be kept. All patient information stored is kept on a password protected computer database or in locked filing cabinets and will not be accessed by anyone outside of the research team. The research team includes members of staff from the NHS and Keele University. If you take part in the telephone interview, this may be recorded. However, only anonymised quotes will be used in any publications.

1. **What if relevant new information becomes available?**

Sometimes we get new information about the treatment being studied. If this happens your research surgeon will tell you and discuss whether you should continue in the study. If you decide not to carry on, your research surgeon will make arrangements for your care to continue. If you decide to continue in the study he may ask you to sign an agreement outlining the discussion.

1. **What if I change my mind about taking part?**

If you initially consent and change your mind prior to the beginning of your treatment you will not take part in the study and the routine management of the condition will continue at the hospital site. This will not affect your standard of care. If you withdraw from the study during the follow up period, you will not be contacted by the research team further, or be required to complete additional questionnaires. However you will be asked if any data collected up to the point of withdrawal can be retained and used by the study team.

1. **Will my GP be informed of my involvement in the study?**

With your permission, we will write to your GP and let them know you are participating in the study.

1. **What will happen to the results of the research study?**

The results of this study will be used to inform the development of a larger randomised trial which will aim to explore this treatment further.

A written summary of the study findings will be drawn up in collaboration with our patient representatives. This can be sent to you if you wish to receive it. If the findings from the study result in a change of practice we will produce information leaflets and posters to help inform future patients.

The research will be published in scientific and health service journals which will be available for access on the web or by request from your local medical library. The results will also be presented at conferences and any recommendations of change to practice will be made available nationally throughout the National Health Service and within the hospital.

1. **Who is organising and funding the research?**

The study is organised and sponsored by the University Hospitals of North Midlands NHS Trust. We have funding from the National Institute for Health Research “Research for Patient Benefit” programme.

1. **Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interests. This study was reviewed by the East Midlands – Leicester South Research Ethics Committee (reference 16/EM/0166). It has also been scientifically reviewed and approved by the Research for Patient Benefit funding body and your local orthopaedic consultant. The study has been approved by the local Research and Development Department at your hospital.

1. **Further Information.**

If you require more information about this study please call one of the telephone numbers provided to speak to a member of the research team.

**THANK YOU FOR READING THIS INFORMATION SHEET**

**If you have any questions or would like more information please contact the MAPP study team or a member of your local study team (see next page)**

**MAPP STUDY TEAM CONTACTS**

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**LOCAL STUDY TEAM CONTACTS**

**Local Study Principal Investigator**

**Local Research Nurse**

**Orthotist**

**Please keep this information for your records.**