

# Back pain prevention in multiple myeloma using an external spinal brace

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<b>Registration date</b> 05/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/05/2019	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Myeloma is a blood cancer that affects several bones, mostly the spine. Around one person in 120-150 is at risk of developing myeloma. Current treatment can control the cancer. However, it does not offer a cure and has little effect on preventing back pain, disability, or spinal deformity – which may need difficult spinal surgery. An external spinal brace during treatment may be able to reduce back pain intensity, help prevent disability, minimise the risk of spinal deformity, and reduce the need for surgery. Managing back pain in myeloma with a brace has not been tested and is not routine practice in other centres in the UK. Therefore, the aim of this study is to find out whether it is possible to run a full study of the brace in multiple centres, which would assess whether using a brace minimises back pain and disability compared to standard medical treatment alone.

### Who can participate?

Patients aged over 18 with myeloma-related back pain

### What does the study involve?

Participants are randomly allocated to receive either standard medical treatment (chemotherapy, pain-killing medication) alone or a brace with standard medical treatment. Participants are regularly assessed at research clinics to determine the number of patients required for the full study. Information is collected to inform a list of requirements a centre needs to have in place to run the full study. The total duration of treatment and follow up is 3 months, and a subset of 20 participants is asked to complete a questionnaire at the end of the 3-month period.

### What are the possible benefits and risks of participating?

Patients with MM are surviving longer, but are often left with a disability due to chronic back pain. The full study will determine whether using a simple low-cost brace can decrease back pain in these patients and improve their disability, thus potentially improving the quality of life of these patients and reducing the cost to the NHS. This study will find out whether the full study is possible and, if so, inform its design.

Where is the study run from?

1. University Hospitals of North Midlands NHS Trust (UK)
2. Royal Wolverhampton NHS Trust (UK)

When is the study starting and how long is it expected to run for?

June 2016 to May 2018

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Mr Sandeep Konduru

## Contact information

### Type(s)

Public

### Contact name

Mr Sandeep Konduru

### ORCID ID

<https://orcid.org/0000-0001-6884-5737>

### Contact details

University Hospitals of North Midlands NHS Trust  
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ST4 6QG

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT02898064

### Protocol serial number

1017

## Study information

### Scientific Title

Back pain prevention in multiple myeloma using an external spinal brace (MAPP) - a feasibility study

### Acronym

MAPP

### Study objectives

Is it feasible to use an external spinal brace to decrease back pain and spine related disability in patients suffering from back pain due to multiple myeloma?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

East Midlands - Leicester South Research Ethics Committee, 27/05/2016, ref: 16/EM/0166

### **Study design**

Randomised controlled multi-centre feasibility trial with two parallel groups

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Back pain in multiple myeloma

### **Interventions**

Participants will be randomly assigned to either control or intervention groups with 1:1 allocation via a computerised random number generator using permuted blocks of random sizes. The randomisation procedure will be conducted by an independent statistician at Keele University and will be stratified by site; block sizes will not be disclosed to ensure concealment. Sealed opaque envelopes containing group allocations will be available at each centre. These will be opened by the research nurse following collection of baseline measurements.

Patients will be randomly allocated to receive either standard medical treatment alone or standard medical treatment plus an external back brace. (Standard medical treatment consists of chemotherapy, radiotherapy, pain killing medication). Patients will be regularly evaluated in research clinics to determine the number of patients required for the full trial. Information will be collected to inform a list of requirements a centre needs to have in place to run an RCT. Total duration of treatment and follow up will be three months for all treatment arms with a subset of 20 participants being asked to take part in a qualitative questionnaire at the end of the 3-month period.

### **Intervention Type**

Device

### **Primary outcome(s)**

1. Time from diagnosis to brace fitting for patients randomised to the intervention group. Dates to be collected by the research team - aim to complete trial recruitment process, i.e. consent to fitting of back brace, within 4 weeks
2. Number of patients in the intervention arm who request additional support from the orthotic team and time they had to wait for support. Dates and information collected by the research team throughout the study at 6 weeks and 3 months
3. The number of orthotists in each hospital and the number and frequency of appointments issued by them. Data collected by the research sites throughout the study
4. The locations and levels of VCFs and back pain in patients and the type of brace fitted will be

recorded to determine whether appropriate braces are fitted. Radiological evidence collected (x-ray and MRI) at 6 week and 3 month follow up

### **Key secondary outcome(s)**

1. The number of new MM cases at each centre and the number eligible for the study during 1 recruitment year, measured at screening
2. The number of eligible patients who give consent to enter the study, measured at screening
3. The number of patients that drop-out during follow-up and their reasons, measured throughout the study until end of recruitment
4. Co-primary outcomes of pain measured by VAS and disability measured by ODI, EQ-5D-5L, measured at 6 week and 3 month follow up
5. Quality of life and pain, measured with a patient questionnaire at 3 month follow up
6. Patient acceptability, measured using semi-structured interviews in a subset of participants at 3 month follow up
7. The number of patients who receive non-study-related interventions during the 3 month follow-up period, measured at 6 week and 3 month follow up

### **Completion date**

31/05/2018

## **Eligibility**

### **Key inclusion criteria**

1. Adults with MM
2. Myeloma infiltration in the spine confirmed by radiological evidence
3. MM-related back pain
4. Can attend for the whole follow-up period
5. Aged >18 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Presenting with cord compression and neurological deficit requiring urgent decompression and intervention
2. Chronic pain syndrome
3. Language barrier that cannot be overcome using translation services
4. Unwilling or unable to give informed consent

5. Painful vertebral compression fractures (VCFs) at the lumbosacral junction (L4 to Sacrum) where application of brace is not possible

6. Not suitable for treatment with a brace e.g. pregnancy

**Date of first enrolment**

03/01/2017

**Date of final enrolment**

28/02/2018

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University Hospitals of North Midlands NHS Trust**

United Kingdom

ST4 6QG

**Study participating centre**

**Royal Wolverhampton NHS Trust**

United Kingdom

WV19 0QP

## **Sponsor information**

**Organisation**

University Hospitals of North Midlands NHS Trust

**ROR**

<https://ror.org/03g47g866>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>		26/08/2016	05/07/2017	No	Yes