

Back pain prevention in multiple myeloma using an external spinal brace

Submission date 12/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/07/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/05/2019	Condition category 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

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

Contact details

University Hospitals of North Midlands NHS Trust
Royal Stoke University Hospital
Newcastle Road
Stoke on Trent
United Kingdom
ST4 6QG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02898064

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional files

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 measure

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

Secondary outcome measures

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

Overall study start date

01/06/2016

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

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**

England

United Kingdom

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

Sponsor details

Newcastle Road
Stoke on Trent
England
United Kingdom
ST4 6QG

Sponsor type

Hospital/treatment centre

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**Publication and dissemination plan**

The study findings will be submitted for publication in haematology and orthopaedic journals as well as general medical journals. The team will approach the organisers of a myeloma patient education day at Myeloma UK and request they become keynote speakers on the potential for use of spinal bracing for reducing back pain for multiple myeloma patients and also to discuss the proposed subsequent full RCT. Such events are frequently attended by nurses, allied health

professionals and service managers directly involved in the clinical pathways for myeloma patients.

The patient representatives are ideally placed to disseminate findings of the research with members of Myeloma UK and will be actively involved in designing the presentations and material to be used for this purpose. The results will also be presented at the British Society for Haematology conference the site requirements needed to partake in the full RCT will be discussed. This may enable the trialists to identify suitable partner sites to take part in such a study.

Intention to publish date

31/05/2019

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?
Participant information sheet		26/08/2016	05/07/2017	No	Yes
HRA research summary			28/06/2023	No	No