

Balloon Kyphoplasty



Myeloma Infoguide Series



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Disclaimer

The information in this Infoguide is not meant to replace the advice of your medical team. They are the best people to ask if you have questions about your individual situation.

Introduction

This Infoguide is written for patients with myeloma, their families and friends. It provides information on a surgical treatment for vertebral compression fractures called balloon kyphoplasty.

This Infoguide reviews what vertebral fractures are, why they more commonly occur in myeloma and the options for treatment. It then describes the balloon kyphoplasty procedure, outlining who could benefit, what it might feel like, what to expect from treatment and what potential problems may occur.

Some of the more technical or unusual words appear in bold the first time they are used and are explained in the medical terms explained section at the back of the Infoguide.

Aims of this Infoguide

- To provide you with more information on balloon kyphoplasty treatment
- To answer some of the more common questions you may have about balloon kyphoplasty
- To help you make informed decisions about the treatment options available

Myeloma UK provides a range of specific Infoguides and Infosheets which cover all aspects of the treatment and management of myeloma. You will find a list of these at the back of this Infoguide.

If you would like a more general overview of what myeloma is, how it is diagnosed, the most commonly used treatments and many of the things you may have to cope with in living with myeloma, please see *Myeloma - Your Essential Guide* and *Living with Myeloma - Your Essential Guide*. To order your free copies contact the **Myeloma Infoline on 0800 980 3332**. This information is also available 24/7 on our website at www.myeloma.org.uk

If you would like to talk to someone about any aspect of myeloma, its treatment and management, call the **Myeloma Infoline on 0800 980 3332**. Your call will be answered by Myeloma Information Nurse Specialists who are supported by medical and scientific advisors. The Myeloma Infoline is open from Monday to Friday, 9am to 5pm, and is free to phone from anywhere in the UK. From outside the UK, call +44 131 557 3332 (charged at normal rate).

What is myeloma bone disease?

Bone disease is the most common and often the most debilitating feature of myeloma and therefore bone pain is a very common symptom. Between 70% and 80% of patients have evidence of bone disease at the time of diagnosis and most will experience bone disease at some point in their illness.

In order to understand more about **vertebral compression fractures** in myeloma it is necessary to understand normal bone activity and the mechanisms that lie behind myeloma bone disease.

Normally, the body is continuously renewing the cells and other materials that help to keep bones strong and healthy. This involves breaking down old bone and replacing it with new bone at the same rate.

Myeloma bone disease is due to the myeloma cells in the bone marrow affecting the surrounding bone, causing the bone to be broken down faster than it can be repaired.

The extent of bone disease varies considerably in individual patients. It most often occurs in the middle or lower back, the hips and the rib cage. The long bones of the upper arm and leg can also be affected.

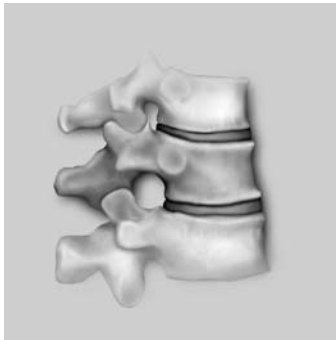
This results in widespread pain. However, it is the lower and middle back that is the most common site of pain. This is caused by fractures in the bones (the **vertebrae**) of the **spine**.

Because the spine bears much of the weight of the body, fractured vertebrae tend to collapse. This is known as a vertebral compression fracture.

This leads to compression of the spinal nerves, causing pain, altered spinal alignment, reduced mobility, height loss, trouble sleeping and a general loss of independence in daily activities.

Figure 1 shows a normal spine and a spine that is misaligned due to a vertebral compression fracture.

1a



1b

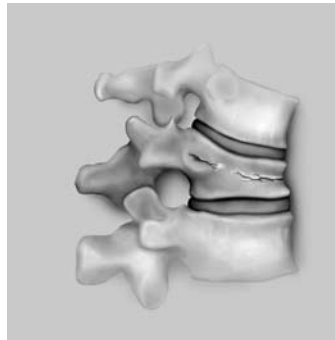


Figure 1a - Normal spine showing three vertebrae, separated by vertebral discs. This spine is aligned correctly.

Figure 1b - The central vertebra has a compression fracture, causing misalignment of the spine. This will cause severe back pain.

What are the treatment options for vertebral compression fractures?

The treatment options for vertebral compression fractures caused by myeloma bone disease include pain killing drugs (**analgesics**), **radiotherapy** and, in some cases, spinal support using back braces or surgical pinning.

Drugs called **bisphosphonates** are effective in preventing and controlling myeloma bone disease and can improve pain and mobility. Two new, more specialised, surgical options also exist - **percutaneous vertebroplasty** and balloon kyphoplasty.

Analgesics

Analgesics are drugs that relieve pain and include aspirin, paracetamol and more powerful painkillers that are available only by prescription. Treatment with analgesics will not prevent further vertebral compression fractures. Myeloma patients should not use over the counter **NSAIDs** such as brufen (neurofen etc) due to the increased potential for kidney damage.

Radiotherapy

Radiotherapy treatment is used to provide short-term pain relief and may also reduce the risk of further vertebral compression fractures by limiting the growth of myeloma in the spine. However, it may take several days for radiotherapy treatment to relieve pain so analgesics are needed as well. Radiotherapy treatment alone does not stabilise vertebral compression fractures.

Bisphosphonates

Bisphosphonates are drugs that slow the breakdown of bone in myeloma. They can significantly reduce bone pain in at least 50% of patients and may reduce the frequency of vertebral compression fractures by up to almost half.

Bisphosphonates also reduce the need for localised radiotherapy treatment.

For more information on bisphosphonates, please see Myeloma UK's Infoguide *Bone Disease and Bisphosphonates*. To order your free copy, contact the **Myeloma Infoline on 0800 980 3332**.

Percutaneous vertebroplasty

Percutaneous vertebroplasty is a relatively minor surgical procedure in which quick-setting bone cement is injected directly into the collapsed vertebra, to stabilise the fracture and so rapidly reduce pain.

For more information, please see Myeloma UK's Infoguide *Percutaneous Vertebroplasty*. To order your free copy, contact the **Myeloma Infoline on 0800 980 3332**.

The rest of this Infoguide concentrates on the role of balloon kyphoplasty as a treatment for vertebral compression fractures due to myeloma bone disease.

As you will see, balloon kyphoplasty is a safe and effective treatment which offers an improvement on the percutaneous vertebroplasty technique mentioned above.

What is balloon kyphoplasty?

Balloon kyphoplasty is a surgical procedure used to treat patients with vertebral compression fractures and the spinal deformity they can cause.

Collapse of the bones of the spine can lead to a progressive spinal deformity, called **kyphosis**, where the spine curves forward.

People with kyphosis have an increased risk of developing more vertebral compression fractures, making their spinal deformity and pain progressively worse.

In some cases, kyphosis can lead to chronic pain, height loss, mobility and breathing problems, and a reduced appetite due to bloating and / or bowel obstruction.

Balloon kyphoplasty aims to correct kyphosis and so improve these complications.

What does balloon kyphoplasty involve?

Similar to the percutaneous vertebroplasty technique mentioned previously, balloon kyphoplasty is a relatively minor surgical procedure that uses cement to expand the vertebra and stabilise the fracture.

However, the balloon kyphoplasty technique offers a potential improvement whereby a small balloon, called an **inflatable bone tamp**, is first inserted into the vertebrae to create a space before the cement is injected. Inflation of the balloon will restore the shape and height of the vertebrae and correct the kyphosis, which cannot be achieved with percutaneous vertebroplasty.

The balloon is then deflated, removed and a precise amount of quick-setting cement is injected in the cavity under low pressure in a controlled manner. This is done to minimise the risk of cement leakage. The cement hardens restoring the shape and strength of the vertebrae.

Balloon kyphoplasty can be performed using a general or local anaesthetic and because it is a minimally invasive surgical procedure, offering fast recovery and mobility, it can be done as a day bed procedure or involve only one night in hospital. Each vertebra can take up to one hour to fix but more than one can be done at a time if required.

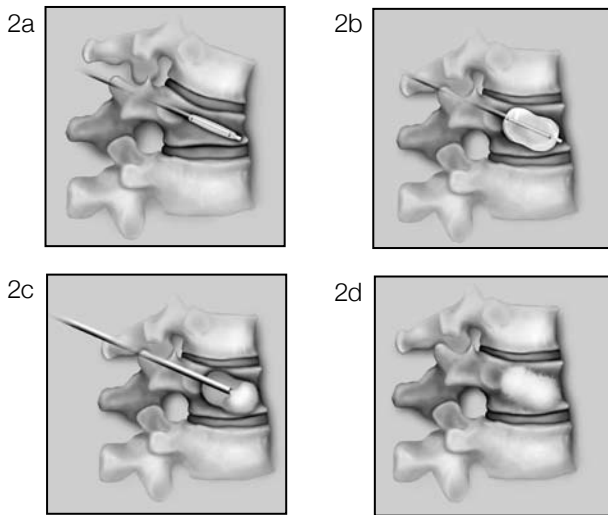


Figure 2a - Through two small incisions, the doctor creates narrow channels into the fractured vertebra and inserts two balloons side by side.

Figure 2b - The balloons are carefully inflated to return the fractured vertebrae to its normal position. The balloons are then deflated and removed, leaving a cavity within the bone.

Figure 2c - The cavity is filled with a quick-setting bone cement to support the surrounding bone and prevent further collapse.

Figure 2d - Once set, the bone cement forms an internal cast that holds the vertebra in place.

It is very important that balloon kyphoplasty is performed by specialist spinal doctors, who are fully trained in the procedure and work in a hospital with all the necessary backup, in case of any complications during the procedure.

Who might / might not benefit from balloon kyphoplasty?

Balloon kyphoplasty is not suitable for all myeloma patients with back pain. Other, more conservative treatments for back pain will usually be tried first.

However, these will need to be monitored carefully to ensure they are working well as vertebral compression fractures often occur suddenly and may cause nerve problems which can have serious and long-lasting effects.

Among the reasons why balloon kyphoplasty may be the right option for you are:

- You have been prescribed conventional treatments for relieving back pain due to vertebral compression fractures and these have not been effective. This means that your pain must have persisted for more than two months after conventional treatment.

However, early and sustained clinical improvements witnessed from published clinical studies for balloon kyphoplasty, suggest a case for early intervention.

- Other causes for your continuing pain have been excluded.

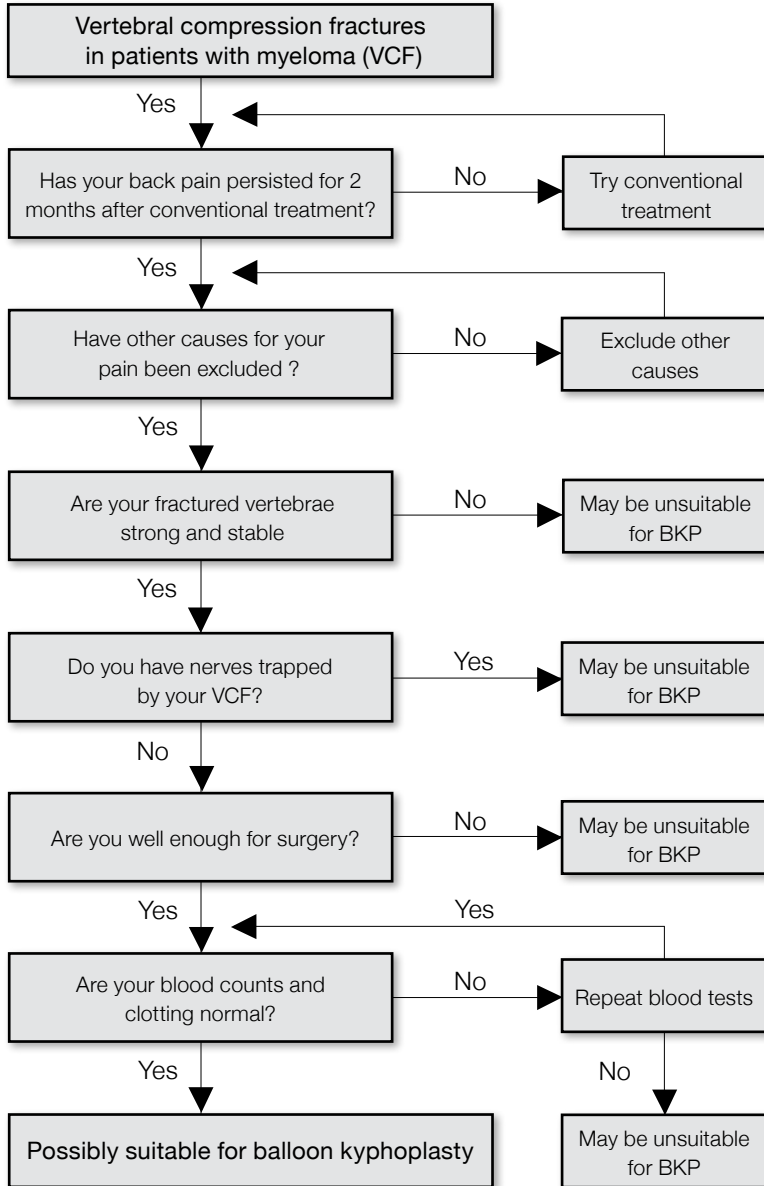
Balloon kyphoplasty is unlikely to be the best option for you if you have:

- A very unstable vertebral compression fracture that would not repair successfully
- Compression of the nerves around the spinal cord
- As per surgical procedures generally, persistently low blood counts or abnormal blood clotting
- An infection in your spine

Balloon kyphoplasty is best performed before radiotherapy as radiotherapy can lead to hardening of the bone, making it more difficult to carry out the procedure.

If you feel you may benefit from this procedure, you should discuss this with your doctor, who will want to take the advice of other healthcare professionals such as nurses, physiotherapists, occupational therapists and surgeons before referring you for balloon kyphoplasty. The algorithm on the following page shows when a vertebral compression fracture might be treated using balloon kyphoplasty.

If balloon kyphoplasty is not an optimal treatment for you, your doctor will discuss other options with you.



VCF Vertebral Compression Fractures
 BKP Balloon Kyphoplasty

What to expect if receiving balloon kyphoplasty

How long does the procedure last?

This will depend on the number of vertebrae being done at any one time but in general terms each will take between 30-60 minutes, depending on the individual case.

What type of anaesthesia is used?

Balloon kyphoplasty can be performed using either general or local anaesthesia; your doctor will determine which is best for you.

How long is the recovery period?

Barring any unforeseen and uncommon complications, you will be able to go home the next again day at the very latest.

Does balloon kyphoplasty work?

Balloon kyphoplasty is a fairly new procedure and it has not been studied widely in myeloma patients. The procedure has been shown to work well in patients with **osteoporosis**, another common cause of vertebral compression fractures.

A recent study in myeloma patients showed that 16 out of 19 patients who had this procedure showed an improvement in their pain and ability to undertake everyday activities.

Although a relatively new procedure, balloon kyphoplasty has been recommended for use on the NHS by the National Institute for Health and Clinical Excellence as part of their interventional procedures programme.

Although this recommendation is not a definitive assessment of the procedure, it should mean balloon kyphoplasty becomes increasingly available on the NHS.

Are there potential risks or side-effects of balloon kyphoplasty?

There are risks associated with any medical or surgical treatment. However, side-effects in patients who have had balloon kyphoplasty are uncommon. Among the possible short-term risks and potential side-effects are:

- Cement leaking from the repaired vertebrae. Balloon kyphoplasty has a significantly lower risk of this when compared to percutaneous vertebroplasty
- Infection (this has not been reported as a consequence of balloon kyphoplasty, but as a consequence of undetected infection already present in the vertebrae before surgery)
- Allergy or other reaction to the bone cement
- Spinal nerve damage

Safety information about new medical treatments is obtained as part of large clinical studies. Because balloon kyphoplasty is relatively new and few studies have been completed, no-one can be sure about the possible medium to long-term risks.

Can balloon kyphoplasty be combined with other treatments?

Yes. Balloon kyphoplasty will not interfere with other treatments you may be receiving for your myeloma and you will be able to continue with your pain and bisphosphonates treatments.

Where is balloon kyphoplasty available?

As already mentioned, balloon kyphoplasty is still a relatively new treatment and is not widely available on the NHS.

The availability of balloon kyphoplasty is, in part, down to accessing the necessary expertise and facilities to carry out the procedure.

For information on which NHS trust, offering a service, is nearest / most convenient for you, please contact the **Myeloma Infoline on 0800 980 3332**.

The future

Clinical studies looking at the effectiveness of balloon kyphoplasty for vertebral compression fractures in myeloma are ongoing.

If these studies show that balloon kyphoplasty continues to be an effective treatment, it should become a much more widely available and established treatment option.

Please contact **Myeloma UK's Infoline on 0800 980 3332** for more details on approved centres recruiting patients for clinical studies.

Medical terms explained

Analgesics: Pain-killing drugs.

Bisphosphonates: Drugs that help to prevent myeloma bone disease.

Inflatable bone tamp: A small balloon that can be inserted into a fractured vertebra and inflated during balloon kyphoplasty.

Kyphosis: Abnormal curvature of the spine.

NSAID: A family of pain killing drugs that also damp down inflammation. Examples include aspirin and ibuprofen.

Osteoporosis: A common condition in which the bones lose strength and fracture more easily. Osteoporosis is especially common in women after the menopause.

Percutaneous vertebroplasty: A surgical procedure for the repair of vertebral compression fractures which involves injecting the vertebra with bone cement to stabilise it.

Radiotherapy: A form of treatment in which high doses of radiation are directed at a tumour to kill it or reduce its size.

Spine: The backbone.

Vertebra: One of the bones of the spine. The plural form is vertebrae.

Vertebral compression fracture: A fracture in one of the bones of the back.

Further information and useful organisations

Cancerbackup

www.cancerbackup.org.uk

0808 800 1234 (Monday-Friday, 9am-8pm)

Cancerbackup helpline workers are trained oncology nurses who can provide information and support to people affected by cancer. Also publish a wide range of patient information.

Cancer Research UK

www.cancerhelp.org.uk

0800 226 237 (Monday-Friday, 9am-5pm)

Its website contains patient information on all types of cancer and gives details of current research and clinical studies.

Leukaemia CARE

www.leukaemiacare.org.uk

0800 169 6680 (24hrs)

The Care Line is staffed 24 hours a day, 7 days a week by trained volunteers who offer befriending, support and information on leukaemia and other blood disorders, including myeloma.

Leukaemia Research

www.lrf.org.uk

020 7405 0101 (Monday-Friday, 9am-5pm)

Leukaemia Research funds research into leukaemia and related blood disorders. They publish a range of patient information, including on myeloma.

Macmillan Cancer Support

www.macmillan.org.uk

CancerLine 0808 808 2020 (Monday-Friday, 9am-6pm)

The CancerLine is staffed by specialist advisors who provide information, practical and emotional support to those affected by cancer.

National Institute for Health and Clinical Excellence (NICE)

www.nice.org.uk

NICE produces guidance on health technologies (the use of new and existing medicines, treatments and procedures) and clinical practice within the NHS. NICE issued new guidance on the use of balloon kyphoplasty in April 2006.

NHS Direct / NHS24

www.nhsdirect.nhs.uk

In England, Northern Ireland and Wales call NHS Direct on 0845 46 47

In Scotland call NHS24 on 08454 24 24 24

Trained medical professionals provide 24-hour access to information on all aspects of health and healthcare.

Pain Concern

www.painconcern.org.uk

01620 822572 (Weekdays 9am-5pm and Fridays 6.30-7.30pm)

Pain Concern provide a range of information about managing pain and self help. Its helpline also offers information, support and a listening ear.

Pain Association (Scotland)

www.chronicpaininfo.org

0800 783 6059 (Monday-Friday, 9.30am-4.30pm)

Its helpline offers support to people with chronic pain. They also run pain management support groups across Scotland.

British Committee for Standards in Haematology (BCSH)

www.bcsghguidelines.com

The BCSH provides haematologists with up-to-date advice on the diagnosis and treatment of myeloma. Its website contains a range of position papers and guidelines relevant to those affected by myeloma, including the *Guidelines on the Diagnosis and Management of Multiple Myeloma*.

UK Myeloma Forum (UKMF)

www.ukmf.org.uk

UKMF is an organisation of people professionally engaged in the field of myeloma who are working to improve the outlook for patients with myeloma and related disorders. On behalf of the British Committee for Standards in Haematology, UKMF has produced guidelines on the diagnosis and management of myeloma.

Kyphon

www.kyphon-eu.com

020 8326 0010

Kyphon develops and markets medical devices designed to restore spinal function using minimally invasive therapies including balloon kyphoplasty.

With Myeloma UK you can...

Call our Myeloma Infoline on 0800 980 3332

You will immediately access information and support relating to all aspects of myeloma. Your call will be answered in confidence by Myeloma Information Nurse Specialists who are supported by medical and scientific advisors. Lines are open Monday to Friday, 9am to 5pm, and are free to phone from anywhere in the UK. From outside the UK call +44 131 557 3332 (charged at normal rate).

Contact us by email

If you have a specific question about any aspect of myeloma, treatment or living with myeloma, you can also contact our Myeloma Information Nurse Specialists by email at askthenurse@myeloma.org.uk

Order our free patient information

Myeloma UK has a range of Essential Guides, Infoguides and Infosheets which give information on myeloma and related disorders, providing details of treatment options and disease management. You will find a list of the information available from us at the back of this Infoguide.

Attend our Patient and Family Myeloma Infodays

These are full-day meetings, where you can learn about the latest in the treatment and management of myeloma from a panel of experts. They are also a valuable opportunity to meet others affected by myeloma.

Subscribe to *Myeloma Matters*

The only myeloma-specific newsletter available in the UK, *Myeloma Matters* offers a fantastic range of features, articles and stories to help you keep abreast of the latest developments in treatment and research.

Visit our website - www.myeloma.org.uk

Developed to provide immediate, 24-hour access to information about myeloma and related disorders to individuals affected by the disease and to the people caring for them.

We need your help

Each year, Myeloma UK sends Infoguides and Infosheets to nearly 10,000 patients and their families, and helps thousands more through providing services such as the Myeloma Infoline and Patient and Family Myeloma Infodays.

That is why we need your help

We depend on the support and generous donations from people like you to provide these important services which are available free to myeloma patients, their families and carers.

Will you help us to help others?

- £5 will pay for an Infopack to be sent to help one more patient
- £20 will allow one of our highly trained Myeloma Information Nurse Specialists to help two callers on our Myeloma Infoline
- £50 will pay for a family of three to attend a Myeloma Infoday
- £250 will pay for 2,000 patient information Infosheets

Simply choose the amount that is right for you, or, if you prefer, choose an amount of your own. To donate you can either post your donation (by cheque or CAF), use your credit card to donate by telephone or use the Myeloma UK website www.myeloma.org.uk

We can make your money go further if you are a UK taxpayer. If you pay tax at the basic rate, we can claim money back for every pound you donate. For example, if you donate £10 then we are able to claim back £2.80, (£2.50 after April 2008) so your donation becomes £12.80 (£12.50 after April 2008). This extra comes from the taxman and doesn't cost you anything. This process is called Gift Aid.

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Other information available from Myeloma UK

Myeloma Infopack

The Myeloma Infopack contains general information about myeloma, treatment options and disease management. It also has information about Myeloma UK and the range of services available to those affected by myeloma.

Booklets

Myeloma – Your Essential Guide

Living with Myeloma - Your Essential Guide

Infoguides

Bone Disease and Bisphosphonates

Chemotherapy

Clinical Studies

High-Dose Therapy and Stem Cell Transplantation

MRC Myeloma IX

Percutaneous Vertebroplasty

Revlimid

Serum Free Light Chain Assay

Thalidomide

Velcade

Infosheets

Infosheet topics include:

Diet and Nutrition; Erythropoietin; Fatigue; Growth Factors; Managing Your Finances (including Benefits); Mouthcare; Pain; Peripheral Neuropathy; Plasmapheresis; Radiotherapy; Steroids; Support Groups; The Kidney; Travel Insurance; Travelling.

Leaflets

Myeloma – An Introduction

There are a number of conditions closely associated with myeloma. Myeloma UK has information available on AL amyloidosis, Waldenström's macroglobulinaemia and MGUS

To order these free publications please contact Myeloma UK.

Myeloma Infoline: 0800 980 3332 (freephone number) or 0131 557 3332

www.myeloma.org.uk email: myelomauk@myeloma.org.uk

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All Myeloma UK's publications reviewed by patients and healthcare professionals prior to publication.

Myeloma Infoline 0800 980 3332

www.myeloma.org.uk



For more information or to access any of the information and support services listed, contact Myeloma UK

Myeloma UK

Broughton House
31 Dunedin Street
Edinburgh
EH7 4JG

Tel: 0131 557 3332

Fax: 0131 556 9720

email: myelomauk@myeloma.org.uk

Myeloma Infoline: 0800 980 3332

www.myeloma.org.uk

Charity No. SC 026116

Annual UK Myeloma Awareness Week 21-28 June