

A NON-INVASIVE TREATMENT FOR
SYMPTOMATIC UTERINE FIBROIDS



MR-GUIDED FOCUSED ULTRASOUND
PATIENT INFORMATION

DO YOU SUFFER FROM UTERINE FIBROIDS?

If you do or know someone who does, then you also know that uterine fibroids can be painful and uncomfortable, cause cramping, abdominal pain, heavy menstrual bleeding, anaemia, frequent urination, constipation and a distended stomach.

Uterine fibroids are the most common benign (non-cancerous) tumour in women. Approximately 20-40% of women older than 35 years old have fibroids. Fibroids occur more frequently in African / Afro-Caribbean women. Fibroids account for many medical visits, tests, medications and medical procedures. They are also a major contributory factor for work absence and reduced quality of life. For instance, heavy bleeding due to fibroids is a major cause of anaemia, usually requiring iron tablets, but sometimes blood transfusion.

Until now, most treatment options for uterine fibroids have been invasive surgical procedures. With MR-guided Focused Ultrasound (MRgFUS) however you have an outpatient, non-invasive alternative without the need for surgery, anaesthesia or hospitalisation.

Based at St Mary's Hospital in Paddington, London, the MR Therapy Centre is a dedicated treatment centre for MRI and MRgFUS. Our medical consultants are among the most experienced doctors world-wide in clinical and research aspects of MRgFUS, having carried out this procedure since 2002. With easy access to public transport facilities, a well equipped outpatient facility and a highly specialised team, the MR Therapy Centre is an excellent choice for your MRgFUS procedure.

WHAT IS MRGFUS?

MRgFUS allows your doctor to see inside your body, find your fibroid and treat it without surgery. Whilst lying in a Magnetic Resonance Imaging (MRI) scanner which provides real-time pictures of your pelvis, very high intensity ultrasound is focused to pre-determined spots on the fibroid allowing thermal destruction, or cell death, to take place. The ultrasound used in this procedure is many times stronger than the ultrasound used in diagnostic imaging.

MRI also provides continuous real-time feedback of temperature changes in the fibroid during treatment to confirm that the appropriate amount of energy is delivered to the correct location of the fibroid. Unlike other radiological techniques, no radiation is used in MRI.

Following the treatment, anatomical MRI images enhanced with a contrast agent (or dye) called gadolinium are used to evaluate treatment outcome by showing how much of the fibroid area has been destroyed.

The time required for this procedure ranges from three to four hours. This is followed by one to two hours recovery time in the MR Therapy Centre. Most women return to normal activity in one to two days. This greatly contrasts to the potential six weeks recovery period for alternative therapy options.

Treatment is carried out in an outpatient setting using only light sedation and mild pain relief. General anaesthetic is not used during the procedure.

WHY CHOOSE MRGFUS TREATMENT OF UTERINE FIBROIDS?

There are several treatments available for uterine fibroids including destruction of the fibroid through uterine artery embolisation (UAE) or myomectomy and hysterectomy. These invasive procedures can be highly stressful, with side-effects and long recovery periods.

MRgFUS is an entirely non-invasive treatment of uterine fibroids which takes place in a private outpatient setting. The maximum duration of your hospital visit will be 5.5 hours. Unlike other fibroid treatments, MRgFUS patients usually return to work within one or two days.

Our MRgFUS equipment has the CE mark for treatment of uterine fibroids in women who wish to retain their fertility, although we do recommend that fertility issues be discussed with one of our physicians. The treatment will not affect your womb or ovaries but as it is designed only to treat fibroid symptoms; it cannot be seen as a method of assisting you to conceive.

WHAT ARE THE LIKELY TREATMENT OUTCOMES?

More than 85% of women report symptomatic improvement on the National Institute of Health and Clinical Excellence (NICE) recommended uterine fibroid specific Quality of Life questionnaire. The outcome of treatment can depend on the size and location of the fibroids and it is possible that not all of the fibroids can be treated. All women undergo pre-screening investigations to assess their suitability for treatment, which includes a gynaecology consultation, and the likely benefit to each individual will be explained at that time.

Research data and publications are widely available on the internet and you may find the following websites helpful:

- www.mrtherapycentre.com
- www.uterine-fibroids.org
- www.fibroidrelief.org

(The MR Therapy Centre is not responsible for the accuracy or content of external websites).

It is important to know that MRgFUS will not remove the fibroid(s) from your body. The treatment is designed to treat the symptoms of fibroids and improve your quality of life by reducing the activity of problematic fibroids. The treatment is particularly successful with painful and prolonged heavy menstrual bleeding, pressure symptoms and urinary and bladder symptoms. Once the fibroid is dead, it will remain in place, with a likely maximum shrinkage of not more than 50%. Commonly, shrinkage is in the region of 10-30%. Shrinkage will not be visible immediately post-treatment with maximal shrinkage at six months after the procedure. After MRgFUS, fibroid tissue does not leave the body via the vagina as in uterine artery embolisation, and this is why women do not experience the painful discharge associated with embolisation after treatment. There are no known effects of the treated fibroid remaining in the body as uterine fibroids are known to be benign.



Of course, MRgFUS can only treat your medical condition as it presents to us at the time you are treated. Because the womb is still intact, the environment that allows fibroids to grow is still intact, so it is possible that new fibroids will grow in the future or any fibroids not treated during your MRgFUS session will grow. It may be possible for treated fibroids to grow back. Treatment is designed to give relief to the distressing symptoms of this condition without surgery and cannot eliminate your chances of ever growing fibroids again. This is true for all uterine fibroid treatments except hysterectomy.

The incidence of post-treatment complications after MRgFUS is very low. We have not experienced the infective morbidity associated with other treatments such as uterine artery embolisation and have never carried out an emergency hysterectomy following this procedure.

WHAT ARE THE SIDE-EFFECTS OF MRGUFUS TREATMENT?

MRgFUS treatment is a less disruptive procedure than the alternative treatments for fibroids. Most patients have no problems following the procedure and are able to return to work in 1-2 days. Patients will usually have only mild lower abdominal discomfort.

Occasionally MRgFUS may cause redness of the skin, firmness in the area of treatment, minor pain, skin burns, bleeding and/or bruising. These effects would be visible immediately after treatment. In most cases it is expected that the effects of this will resolve in 10 days. More serious skin burns are rare.

Some patients may have more severe problems, however, this is unusual. A few patients have complained of irregular menstrual bleeding for a few weeks after the procedure and in all cases, this has settled without treatment. Some women experience feelings of bruising or are sore for a few days following the treatment. On rare occasions, this lasts for 2-3 weeks.

There have been no cases of infection following this procedure, except minor urinary tract infections caused by catheterisation. These are easily treated with antibiotics. The MR Therapy Centre remains vigilant regarding more serious infection, as this has occurred with some other types of fibroid treatment. This has not yet occurred in any of our patients following MRgFUS.

Although MRgFUS treatment has been successfully performed for several years at St Mary's Hospital, we are continuing to learn how different people react. We are very keen to keep in contact with all women who undergo this treatment in the MR Therapy Centre in order to build up our knowledge.

ARE THERE SOME PEOPLE WHO ARE NOT SUITABLE FOR TREATMENT?

Some patients will not be suitable for MRI scanning which is part of the MRgFUS treatment. MRI scanning should not be used when there is the potential for an interaction between the strong MRI magnet and metal objects that might be imbedded in your body. The force of magnetic attraction on certain types of metal objects

(including surgical steel) could move them within the body and cause damage. Metal may be imbedded in a person's body for several reasons:

1. **Medical:** People with implanted cardiac pacemakers, metal aneurysm clips, or broken bones repaired with metal pins, screws, rods or plates must tell the radiologist prior to having an MRI scan. In some cases (like a metal rod in a reconstructed leg) the difficulty may be overcome.
2. **Injury:** Patients must tell the doctor in advance if they have bullet fragments or other metal pieces in their body from old wounds. The suspected presence of metal, whether from an old or recent wound, may need to be confirmed before scanning by a simple x-ray.
3. **Occupational:** People who have significant work exposure to metal particles (working with a metal grinder, for example) should discuss this with their doctor prior to treatment. The patient may need pre-scan testing – usually a single x-ray to the eyes to see if any metal is present.
4. **Other:** Treatment cannot be carried out if you may be pregnant. You should also advise us in advance if you are breast-feeding.

Please note that there is a maximum weight limit for the scanner which is 95kg. Where patients are at the upper weight limit, we will need to ensure that the procedure is safe to carry out in terms of ensuring safe positioning in the scanner before treatment goes ahead.

Patients who are claustrophobic (uncomfortable in confined spaces) may not be suitable candidates for treatment. However, relaxation medication is provided which may help you continue with treatment. Throughout the procedure you will be in constant contact with our treatment team, and will be able to stop the treatment at any time using a hand-held shutdown control.

We cannot treat patients who have vertical abdominal scarring between the belly button and pubic bone. Scar tissue collects heat and increases the risk of skin burning which would render the use of MRgFUS in this case completely non-viable. Women who have had standard low, horizontal caesarean sections can usually receive treatment, as can women who have scarring to the side. We would need to be aware of any scarring on your stomach region as we would need to assess the scar in relation to the location of the fibroids to confirm whether the treatment could be performed. If you are concerned, you should confirm with the MR Therapy Centre first.

MRgFUS is designed to treat the symptoms of fibroids causing fibroid cell death, without removing it from the body. It is therefore not suitable for women who wish to have the fibroid completely removed from the body. Although shrinkage will occur, this may be minimal in some cases.

MRgFUS cannot treat cysts, endometriosis or adenomyosis.



WHAT IS THE PROCESS FOR ASSESSING SUITABILITY OF TREATMENT?

As is the case with all procedures, not everyone will be suitable for MRgFUS. In some cases we can rule out candidates immediately and you should check the section titled "Are there some people who are not suitable for MRgFUS?"

In order to determine suitability, all potential candidates will be required to undergo a gynaecology assessment and MRI scan at St Mary's Hospital. Private and NHS appointments can be booked on receipt of a doctor's referral letter for consideration of MRgFUS of uterine fibroids. This should be posted or faxed to:

Professor W. Gedroyc
Consultant Radiologist
MR Therapy Centre
Clarence Wing Basement
St Mary's Hospital
Praed Street
London, W2 1NY

Fax: 0207 886 7607

Private patients will be contacted within 24 hours to make an appointment in the MR Therapy Centre. NHS referrals will be passed to the St Mary's Hospital gynaecology team who will normally send out an appointment within 8 weeks.

It is possible that we may be able to review recent MRI images taken at other sites. There is a charge for this service and you should telephone Reception in advance on 0207 886 7605 to discuss arrangements for this.

WHAT HAPPENS ON THE DAY OF THE MRGFUS PROCEDURE?

Once you have undergone the relevant MRI and gynaecology pre-assessments, you will be contacted to make an appointment for your MRgFUS treatment. Your treatment will take place in the MR Therapy Centre, a private outpatient centre at St Mary's Hospital. On the day of the treatment, you will be met by the physicians performing the procedure who will discuss the treatment with you again and ask you to sign a consent form. Your safety on the MRI scanner will be reassessed.

Medicine will be given to you through a small tube in your arm or hand vein (intravenous) to help you relax and to decrease any discomfort from the treatment. You will have a catheter placed in your urethra to help keep your bladder empty throughout the treatment.

You will be asked to lie down on a specially adapted MRI bed on your stomach. An MRI scan will be performed to reconfirm the exact location of the fibroid(s) before treatment starts. The doctor will use the MRI pictures to plan your treatment and control where the ultrasound beam is aimed.

Following this planning stage you will undergo MRgFUS treatment. During the treatment a number of short ultrasound pulses will be aimed into the fibroid to heat up the fibroid cells. This amount and type of heating causes damage to the cells until they die. During each ultrasound pulse, more MRI pictures will be made to confirm

where the heating has taken place. The doctor will check the pictures after each pulse to make sure that the treatment is occurring as it should.

Throughout the treatment you will be asked how you are feeling. Your vital signs (pulse, and the level of oxygen your blood is carrying) will be measured. The treatment will be stopped if you say that it hurts too much or if you find that you do not want to continue the treatment. You will also have the ability to stop the treatment yourself if it becomes too uncomfortable by using a handheld shutdown control.

As soon as the focused ultrasound treatment is completed, you will have another MRI scan with dye so that the doctor can examine your fibroid again and monitor the changes in it from the treatment. They will know immediately how successful the treatment has been.

We usually allow one to two hours of recovery time following the treatment, where you will be provided with food and we monitor how you are feeling. You will be able to walk following the treatment, although as medication is provided which may cause drowsiness, we ask that all patients are met by a friend or relative at the unit following their treatment.

It is recommended that you see your referring gynaecologist six-months after treatment to monitor how you are feeling. Appointments can be organised more quickly if you are worried about your symptoms.

Because we are still monitoring the progress of the treatment, we ask patients to fill in anonymised questionnaires before and after treatment which quantify their symptoms over a period of time. We would like to keep in contact with all patients to monitor their long-term response to treatment.

HOW MUCH DOES MRGFUS COST AND ARE THERE ANY CLINICAL TRIALS?

MRgFUS treatment is currently only available privately. Pre-investigations however (i.e. gynaecology assessment and MRI) can often be carried out on the NHS or privately. The current cost of treatment, and payment methods, are available on our website – www.mrtherapycentre.com. Our website also has the current cost of a one-part MRI scan to assess your suitability for MRgFUS.

Some NHS patients may be eligible to apply to their Primary Care Trust for "exceptional circumstances" funding of the procedure. You should discuss your eligibility for this during your gynaecology consultation at St Mary's Hospital.

From time-to-time, we may be conducting clinical trials that require patient participation. Details of these trials will be made available on our website.



FURTHER INFORMATION

We would be happy to answer any further queries you might have about this treatment. Please contact us on 0207 886 7605 or email reception@mrtherapycentre.com.

The National Institute of Health and Clinical Excellence (NICE) published their clinical guidance on MRgFUS in September 2007. This is available to download and review via the following link: www.nice.org.uk/guidance/ipg231
(The MR Therapy Centre is not responsible for the content and accuracy of external websites).

You may wish to discuss this treatment with your GP or gynaecologist and we will be happy to send them more information. However, they will not be able to assess your suitability for treatment and you should follow the advice in this information sheet if you would like to undergo MRgFUS for uterine fibroids.

*The MR Therapy Centre is operated by Saint Mary's Therapy and Imaging Ltd
Registered in England Number: 5858898*





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