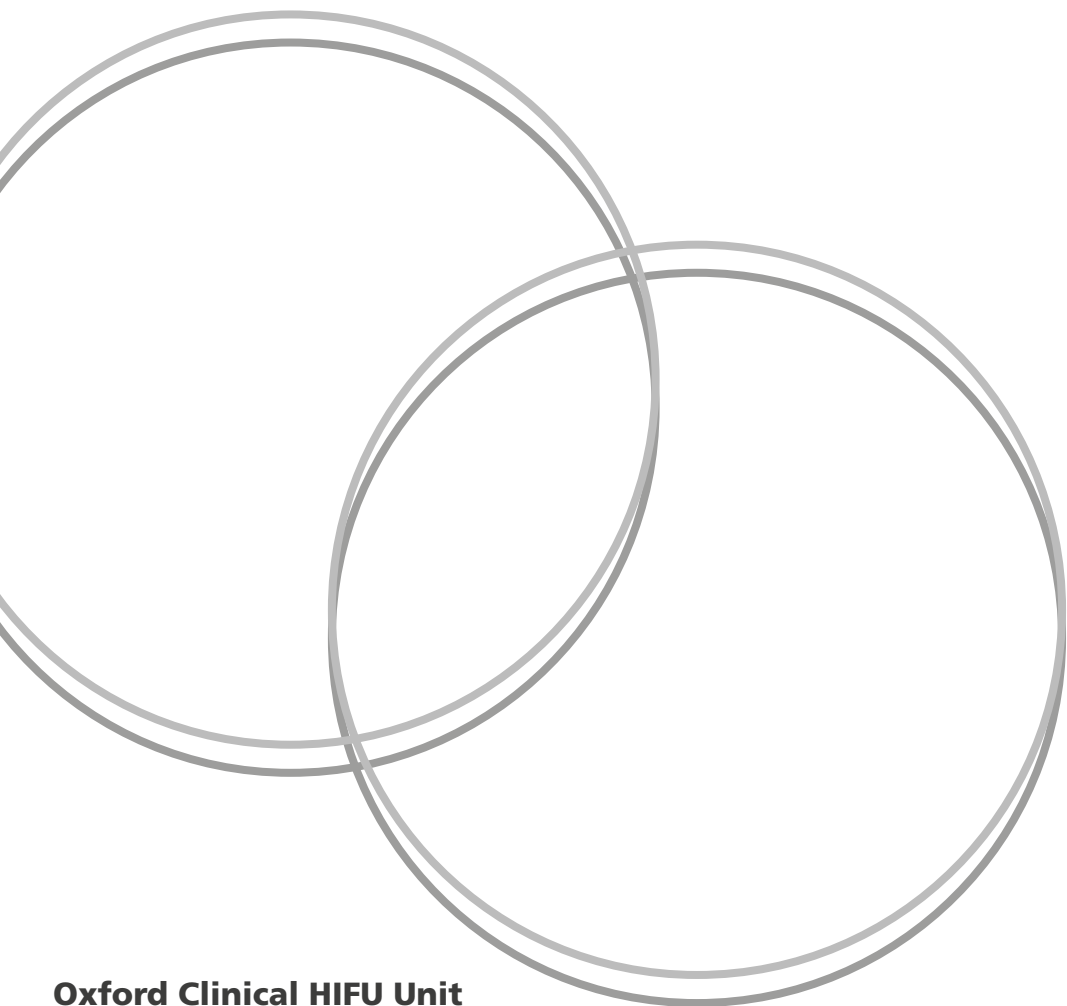




Oxford University Hospitals  
NHS Foundation Trust

# High Intensity Focused Ultrasound for Uterine Fibroids

Information for patients



Oxford Clinical HIFU Unit

Fibroids are non-cancerous growth made of muscle tissue, that develop in the uterus. They can cause symptoms depending on size and location.

## **What are Uterine Fibroids?**

Fibroids are the most common tumours in women of reproductive ages. They affect approximately 1/3 of women aged 35. Although they are benign (noncancerous), they can cause significant health problems for women with symptomatic fibroids.

These symptoms can include:

- abdominal pain and sensation of bloating
- heavy and painful periods
- heavy menstrual bleeding
- difficulty with urination (and severe cases can cause urinary tract obstruction)
- infertility.

Women with fibroids often have to visit their doctor regularly and require many tests and investigations. Furthermore, due to the severity of their symptoms, affected women may have to take frequent sick days from work, as well as their home and family life being affected. These problems are costly to those affected and the health care system.

Larger fibroids are more likely to cause severe symptoms. There is good evidence that reducing the size of uterine fibroids can reduce symptoms significantly.

# What are the treatments for Uterine Fibroids?

## **Medical treatment (hormone manipulation):**

- GnRH agonists – these act to bring on menopause, which is reversed when the medication is stopped.

## **Non-medical treatment**

- uterine artery embolisation
- myomectomy (remove the fibroid and leave uterus intact)
- hysterectomy (remove entire uterus)
- high intensity focused ultrasound (HIFU).

## **What is HIFU?**

A relatively new clinical technology, involving high energy focused sound waves (focused ultrasound), allows us to induce high temperatures to destroy a precise volume of the target tissue without harming surrounding structures. This is similar to focusing sunlight using a magnifying glass. It allows high temperatures to destroy tissue at accurately points without damaging intervening or surrounding tissue.

In Oxford we use ultrasound-guided HIFU (HAIFU™ JC200-Focused Ultrasound Therapy System). The device has been clinical approved for tumour therapy and in China Focused Ultrasound devices have been used to treat in excess of 100,000 patients with uterine fibroids. Previous studies, using a similar device at the Royal Marsden Hospital and the Institute of Cancer Research, UK, have shown that focused ultrasound is safe and has minimal or no side-effects, and may offer advantages over existing treatments. At the Churchill hospital in Oxford, the JC200 device is being used to treat patients for fibroids and for some cancers. Some such treatments are performed as part of clinical trials, but at present fibroid treatment is not under a trial.

## **How can HIFU treat my fibroid(s)?**

The JC200 focused ultrasound device uses ordinary diagnostic ultrasound to view organs and structures within the body to allow fibroids to be targeted. High energy ultrasound is then emitted from the same device to destroy the fibroid tissue. The same diagnostic ultrasound is used to monitor the real-time progress of the treatment.

HIFU treatment of uterine fibroids usually takes 3 to 4 hours in total. It is performed under light sedation to keep you relaxed and pain free during the procedure. You will not normally require a general anaesthetic. You will need to lie on your front on the HIFU device and the HIFU ultrasound energy passes through a water bath and then through your body into the fibroid. Typically we will monitor you overnight after your treatment; if all is well, you will be able to go home the next day. In some case we may discharge you the same day.

The treatment is designed to shrink the size of your fibroid(s) in order to improve your symptoms. It does not remove the fibroid from your body as surgery would and therefore further growth of the fibroid can occur in the future.

## **Why should I choose HIFU for my fibroids?**

There are a number of treatment options for your fibroids and you should discuss all of these with your gynaecologist. Hormonal manipulations are the least invasive treatment. However these may not be entirely effective and have side effects. Surgical procedures may be more effective in terms of definitive treatment, but are invasive and associated with a different set of side effects. Uterine Artery Embolisation (UAE) is a minimally-invasive treatment which blocks off the blood supply to your fibroid, making it shrink in size. This is effective but may result in post-procedure pain and vaginal discharge. Removal of the fibroid (myomectomy) is effective and can be performed with keyhole surgery to improve post-operative recovery and pain. However heavy bleeding is a potential complication. Removal of the entire uterus (hysterectomy) will cure your condition completely but is only suitable if fertility is no longer desired.

Non-invasive HIFU treatment is designed to shrink your fibroid(s) by destroying the tumour and its blood supply. It leaves the uterus intact and will not negatively impact your fertility. Heavy bleeding and vaginal discharge do not occur following HIFU. It is not designed to treat the entire fibroid or to remove it surgically. Some of each treated fibroid will remain in place and further growth may occur in the future. The treatment is aimed at improving your symptoms without the need for surgery, tablets or implants. Each treated fibroid shrinks by approximately 10 to 50% after HIFU. It is possible to repeat HIFU in the future if your symptoms recur. HIFU treatment does not involve ionizing radiation.

## **How effective is fibroid HIFU?**

Fibroid HIFU is a relatively new treatment but several different units have reported good results. 70 to 90% of women report an improvement in their symptoms using a validated questionnaire. Treatment outcomes depend on a number of factors. These include the number and size of fibroids present. We may not treat all your fibroids in a single treatment session – if there are several we will target the largest one(s) as these are most likely to be causing your symptoms.

## **What happens prior to my treatment?**

We must receive a formal referral from your gynaecologist before we can consider you for HIFU. We will ensure that we have an up-to-date MRI of your pelvis with contrast prior to being listed for HIFU as this is required both for planning purposes and to compare with post-HIFU imaging to look for response to HIFU.

Prior to treatment you will be invited for a HIFU planning session during which time you will be assessed for suitability to treatment and this is also a good opportunity to discuss any outstanding questions. After discussion, you will be asked to complete the Uterine Fibroid Symptom and Quality of Life Questionnaire Form (UFSQOL) as a pre-HIFU assessment regarding the symptoms of your fibroid(s). We recommend bringing spare underwear for this planning session, as it will involve you lying in the HIFU water bath, similar to a treatment.

As the HIFU procedure is carried out in the face-down position for several hours, we would suggest that you practice to lie on your front on your bed for a couple of hours at home every day for a week before HIFU treatment. This will train your body to be more comfortable in this position at the time of treatment.

## **How do I prepare for my treatment?**

Prior to your treatment the HIFU team will prescribe medication (usually two sachets of Picolax) to prepare (empty) the bowel which can be collected from pharmacy at the Churchill Hospital. Preparation of the bowel is essential to minimise risk of damaging the bowel or rectum on the day of HIFU.

If you are prescribed Picolax for a morning HIFU treatment the first sachet should be taken as per the instruction at 6pm on the evening prior to the day of treatment and the second sachet at 6am on the morning of treatment. If your treatment is in the afternoon then you should take your first sachet at 10pm on the evening prior to the day of treatment and the second sachet at 10am on the morning of treatment.

Other than clear fluids (e.g. water, squash, black tea or coffee) up to 2 hours prior to your procedure, you should be nil by mouth for 24 hours prior to your HIFU procedure. You should not take large-dose carbohydrate loading drinks prior to your period of fasting as these may lead to low blood sugar levels following your period of fasting.

## **What happens during my admission?**

On the day of treatment, or the night before, you will attend the hospital ward that will be caring for you. You will be prepared for your procedure by the nursing staff and your doctor(s) will see you and ask you to sign a consent form.

As fibroids can lie close to the wall of the bladder, you will have a urinary catheter (urinary tube) inserted shortly before the treatment. This will allow us to control the contents of your bladder during the treatment session to ensure optimal position of the fibroid(s).

We will then take you to the Oxford HIFU Unit for your treatment – a short walk from your hospital ward. You will be asked to lie on the HIFU therapeutic device on your front, so that your lower abdomen and pelvic area are immersed in a water bath. The focused ultrasound will come from a disc (transducer) at the bottom of the water bath and travel through the water, through your skin and finish at a focused area in the fibroid. The treatment will normally take between two and four hours from start to finish, depending on the size of your fibroids and how many fibroids are treated in one session.

A small drip (cannula) will be inserted into your arm and a sedative medication will be continuously administered during your procedure. You will be awake enough to talk to your doctors but sufficiently relaxed to allow the treatment to take place. During the procedure, we will check your blood pressure, pulse rate and blood oxygen levels. We will carefully treat your fibroids using the device; should you experience any discomfort then we will give you additional pain killing medication.

During the treatment your lower legs may be fitted with compression stockings and a specialist pneumatic compression device. This is to help avoid having deep vein thrombosis as a result of lying in the same position for several hours during the treatment session.

Following your HIFU treatment, we will transfer you back to your hospital ward for your recovery, during which time your blood pressure, pulse and blood oxygen levels will be monitored until you are discharged by your doctor, usually the next day.



## **What about my recovery?**

Generally, you will be discharged the day following your treatment session following a clinical review. You may experience some mild pain in the first few days of your recovery. If this occurs, you should take an over-the-counter pain-relieving medication such as paracetamol.

We ask that you do not drive (nor will you be insured to) or engage in any other risky activity for over 48 hours after your HIFU treatment. We normally recommend a few days off work following the procedure to allow you to rest. You may find that you have some slight disturbance in bowel or bladder function following your treatment, which will normally settle in a few days.

If you have any increasing abdominal pain, fevers/shivers/temperatures, nausea/vomiting or notice bleeding in your urine or stool following your treatment you should seek urgent medical advice either through our department, your GP or emergency services if out of hours or depending on your location.

## **Follow-up after your treatment**

At around three months after your treatment, we will arrange a follow-up contrast MRI scan to determine the effectiveness of your treatment. If you are having problems before this date, an earlier appointment can be arranged. Your scan results will be discussed with you in due course and potentially further treatments may be arranged following consultation.

# **What are the side effects of HIFU treatment?**

HIFU has been used to treat many diseases including tumours in the kidney, pancreas, liver, prostate and the uterus. HIFU is a generally safe procedure and serious side effects are very rare. We want you to feel confident in your decision to have HIFU and we have therefore outlined any potential problems that can occur following your procedure. We have also tried to guide you as to how common these problems are.

## **Discomfort**

We would normally expect some minor pain and discomfort at the time of treatment. Generally standard pain-relief given intravenously during the treatment will alleviate these symptoms. Most women experience some lower abdominal discomfort for up to a week following their treatment. Simple over-the-counter pain relieving medication should alleviate this if required.

## **Skin damage**

It is possible that some heating of the skin may occur during treatment. Occasionally, skin redness, firmness or mild blistering may occur. This is visible straight after the treatment and is similar to sunburn. This is likely to resolve fully (without scarring) within 1 week. More serious skin burns can occur, including those that leave permanent scarring. However, serious burns are rare and occur in less than 1 in 100 cases.

## **Irregular bleeding**

As a general rule your treatment should be scheduled not to coincide with your period. This is because it is thought that treatment during menstruation may increase the chance of bleeding or infection following your treatment. Although your condition may often cause an irregular cycle, if you believe that your treatment date will coincide with your period please let the HIFU team know as soon as possible. There have been no reported cases of developing a collection or abscess in the fibroid tissue following HIFU treatment.

Occasionally irregular menstrual bleeding may occur following your procedure. This settles without treatment.

## **Damage to other structures**

There is a very small risk of damaging normal tissues, such as the bowel, bladder, rectum or sciatic nerve if these fall within the region of focused ultrasound beam; this has only occurred in less than 0.1% of the patients treated to date. Careful planning, precise targeting using diagnostic ultrasound and treatment under light sedation to allow patient feedback help us to keep this risk to an absolute minimum.

No other direct complications of the treatment have been recognised, but if you were to experience unexpected symptoms in the first two weeks after your treatment you should seek medical advice.

## **Is fibroid HIFU suitable for everyone?**

Not everyone can have HIFU treatment for fibroids. It is crucial that we can accurately see your fibroids using our ultrasound device before we can embark on any treatment. If this is not possible we cannot safely treat your fibroids.

Women who are significantly overweight may be difficult to treat. This is because fat tissue builds up in the lower abdominal wall and may prevent delivery of sufficient HIFU energy to the fibroid as well as increasing the risk of serious skin burns. It is likely that women over 100kg will be unsuitable for HIFU treatment.

Women with midline vertical scars over the lower abdomen may not be suitable as scar tissue absorbs more HIFU energy. This prevents HIFU reaching its targets and increases the risk of serious skin burns. Women with these types of scars are not suitable for HIFU. However, women with horizontal (transverse) scars over the lower abdomen can be treated as these scars are thinner and absorb less HIFU. The scar following caesarean section is an example of a lower horizontal scar.

## **What can I do after my HIFU treatment?**

We expect you to feel back to normal after just a few days. You should perform only light activities during these first 48 hours. After this, you can return to normal activities including exercise, but we would recommend avoiding strenuous exercise for at least a week.

Remember to be guided by your body. If you are feeling discomfort then refrain from strenuous activities such as heavy lifting or exercise.

## Is fibroid HIFU available on the NHS?

Oxford is one of the world's leading HIFU units, established in 2002 and recognised by the Focused Ultrasound Foundation as a Centre of Excellence in 2023. We are in discussion with both the NHS and private insurance companies about funding for this treatment, which at present may or may not be available on the NHS or covered by private insurance.

We hope in the near future, fibroid HIFU will become a standard treatment for this problematic condition. As such, your views on your treatment and outcomes are helpful to us and we would like to keep in touch with you after your procedure.

## Further information

We are happy to answer any queries you may have. Please contact Dr. Lyon's secretary via email or telephone as the first point of contact.

The National Institute for Clinical Excellence (NICE) have published Clinical Guidance on Ultrasound-guided HIFU Treatment for Symptomatic Uterine Fibroids and can be found at:

Website: [www.nice.org.uk/guidance/ipg657](http://www.nice.org.uk/guidance/ipg657).

Please also feel free to discuss this treatment with your GP. Your GP may be able to provide general advice about fibroid treatment but it is unlikely to have experience of fibroid HIFU. Specific questions about fibroid HIFU are best directed to either your gynaecologist or to the Oxford Clinical HIFU unit.

### Clinical HIFU Team:

Prof Feng Wu (Professor of HIFU surgery)

Prof David Cranston (HIFU Clinical Director and Surgeon)

Dr Paul Lyon (Associate HIFU Clinical Director and Radiologist)

Dr Priynaka Reddy (HIFU Gynaecology Radiologist)

Dr Shaun Scott (Anaesthetic Consultant)

Dr Andris Klucniks (Anaesthetic Consultant)

Website: [www.nds.ox.ac.uk/research/hifu](http://www.nds.ox.ac.uk/research/hifu)

# Contact details

## **HIFU Secretary**

Email: [Samantha.Messenger@ouh.nhs.uk](mailto:Samantha.Messenger@ouh.nhs.uk)

## **Department of Radiology**

Churchill Hospital  
Oxford OX3 7LE

## **Main Switchboard**

Telephone: 01865 741 841

## **Secretary**

Telephone: 01865 235 746



## Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

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