

Radical radiotherapy treatment for bladder cancer

Consent to treatment



Introduction

The name of your treatment is radical radiotherapy for bladder cancer.

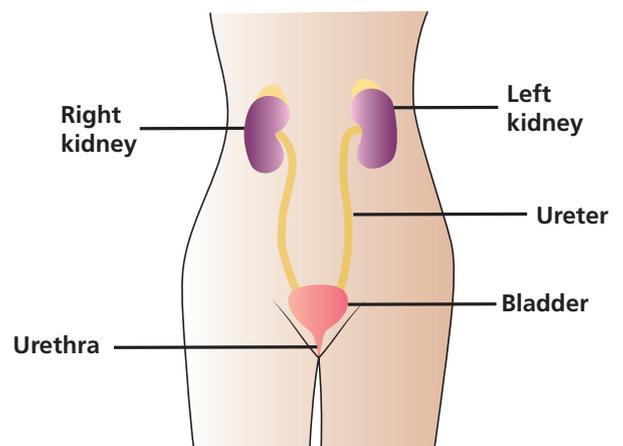
Before you agree to have the treatment you should have a good understanding of the procedure and the possible side effects. This leaflet should supplement the discussion you may have already had with your Clinical Oncologist (a doctor specialising in radiotherapy cancer treatment) and the rest of the team, including therapeutic radiographers (specialist staff who deliver radiotherapy) and nurses. Please ask if you have any questions or concerns which have not been answered. If you hear any words or phrases that you do not understand, please ask your doctor or a member of the healthcare team what they mean.

If you have any additional needs (physical, religious, cultural, emotional or medical), please inform a member of staff so that every effort can be made to meet your individual needs.

Once the treatment and its risks have been explained to you to your satisfaction, you will be asked to sign the form at the end of the document (the consent form). Signing a consent form still allows you to stop your treatment, though it is advisable to complete the course. If you are considering stopping treatment please discuss this with your oncologist.

What is bladder cancer?

Your bladder is part of the body system that filters waste products out of your blood and makes urine. Your kidneys filter your blood and make urine. The urine is carried to your bladder by two tubes called the ureters. Your bladder is like a balloon which stores urine. It is a stretchy bag made of muscle tissue which can hold up to 600ml of urine.



Bladder cancer can develop when cells in the bladder start to grow in an uncontrolled way. Muscle invasive bladder cancer means that the cancer has spread into or through the muscle layer of the bladder.

How is it treated?

Muscle invasive bladder cancer that has not spread to other areas of the body can be treated with radiotherapy or surgery.

In some instances, a radiosensitiser is recommended in combination with the radiotherapy to improve the chance of cure.

Radiosensitisers can make tumour cells more sensitive to the effects of radiation. This can be given as intravenous chemotherapy or a combination therapy with tablets (Nicotinamide) and Carbogen (concentrated oxygen). Your doctor will advise if any of these treatments are appropriate for you.

The recommended radiotherapy course is usually 4 weeks (20 sessions).

What are the benefits of this treatment?

The aim of treatment is to cure you of bladder cancer or to achieve long term local control of bladder cancer.

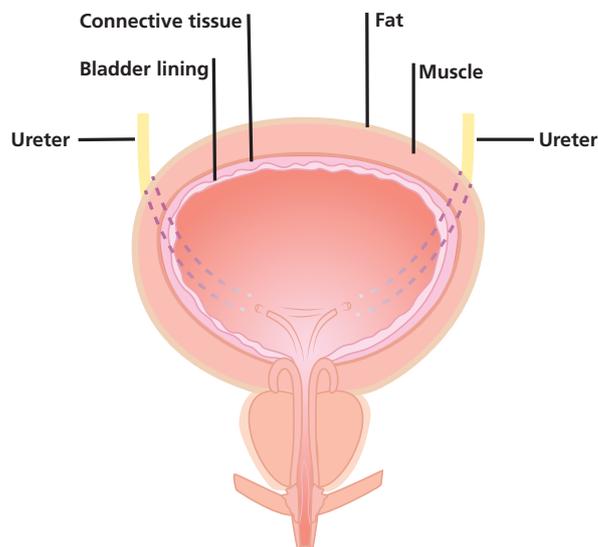
What is radiotherapy?

Radiotherapy is the use of high energy x-rays, to treat the cancer. The organs and tissues of your body are made up of tiny building blocks called cells. Radiotherapy causes damage to the cancer cells in the treatment area. Although normal cells are also affected, they can repair themselves and are able to recover over time. There is a risk of permanent damage to normal tissues, which will be explained further in the side effects section of this leaflet.

Radiotherapy itself is painless and does not make you radioactive. It is perfectly safe for you to be with other people, including children throughout the duration of your treatment. Although only you can be in the treatment room when the radiotherapy machine is on.

Treatment is delivered by a machine called a linear accelerator, also known as the treatment unit or LINAC, shown here.

Please be aware that the radiotherapy centre is a training centre for radiographers as well so students may be present on the treatment unit. However, they are supervised at all times. If you do not wish students to be present during your treatment then please speak to a member of staff. This will not affect your treatment or care.



Planning your treatment

After seeing your doctor in clinic you will receive an appointment to visit the radiotherapy department at Weston Park Hospital for radiotherapy planning.

Your first radiotherapy appointment may include:

- Having a 'planning' CT scan
- Signing the consent form at the end of this leaflet (if it has not been done already)
- Having blood tests

As part of your treatment you will need to have a planning CT scan which is used to identify where the cancer is, so that your radiotherapy can be accurately delivered to this area. The planning scan usually takes 20-25 minutes. You will be asked to loosen your clothing, and to lower your trousers and underwear to mid-thigh. However, the radiographers will ensure that you are covered at all times.

The scan is taken with you lying flat. You will be required to stay very still in this position for each treatment, so it is important that you are as comfortable as possible. If you find this position uncomfortable then please let the radiographers know.

Once you are in position, the radiographers will ask your permission to draw some marks on your skin. These marks are used as a reference point and are to help place you in the correct position for treatment every day. At the end of the scan the marks will be replaced by permanent marks (tattoos). The tattoos are no bigger than a freckle and will be used each day for your treatment. You can wash as normal without worrying about them coming off.

The process of planning your treatment can take about 2-4 weeks. You will have an additional appointment prior to the start of radiotherapy to see the doctor or a member of their team to discuss the radiotherapy treatment and sign the consent form.

What happens during your treatment?

When you arrive for radiotherapy you should go to the reception on the lower ground floor and book in at the radiotherapy reception desk. You will be asked to take a seat in the waiting area.

On the first day of treatment a radiographer will meet with you and have a discussion to explain the possible side effects of treatment and how to minimise them and answer any questions/concerns you may have.

You can expect to spend 15-20 minutes each day in the treatment room. The treatment machine is only switched on for a fraction of this time. For most of the time the radiographers are carefully placing you and the machine, in the correct position for your treatment. The radiographers will do scans before your treatment to ensure that you are in the correct position. You will be in the same position you were in for your CT planning appointment, on your back. The machine does not touch you. It is important for you to stay as still as possible but breathe normally. Once you are set up in the correct position the staff will let you know that they are leaving the room for a few minutes to start treatment.

The machine is controlled by the staff outside in the 'control area' and the machine will rotate around you in different directions. The radiographers are watching you at all times on TV monitors. If you want to stop the treatment at any time, just lift your hand to attract their attention. The TV images

are not recorded or saved. If you need attention the machine will be stopped and the radiographers will come back into the room.

You will not feel or see anything during the treatment however you may hear a buzzing sound when the treatment is being delivered.

You will also have several sets of images taken during your treatment to ensure that the radiotherapy is being delivered accurately to the right area. These images are necessary, but will result in a small dose of additional radiation which has been agreed by your doctor. Any risk from this dose is far outweighed by the benefits to you during your radiotherapy

Side effects and complications of radiotherapy

Side effects can be divided into short term effects that happen during or soon (weeks) after treatment and long term effects which can occur months or years later. Some are common; others are potentially serious but rare.

Below is a list of side effects along with how likely it is for that particular side effect to occur. Here are some definitions to help you:

- **Common** – More than 10 in every 100 (>10%) people will develop this side effect
- **Occasional** – Between 1 and 10 in every 100 (1-10%) people will develop this side effect
- **Rare** – Less than 1 in 100 (<1%) people will develop this side effect

However, please be aware that each patient can react differently to the treatment. You may experience side effects at different times and to varying degrees, compared to other patients having the same treatment.

Short term side effects:

Common ones:

Tiredness (fatigue) - Nearly all patients undergoing radiotherapy will feel more tired than usual. This can be most noticeable towards the end of the treatment and often continues for a week or two after its completion. It may affect your ability to drive (although to be this severe would be rare). This fatigue is usually a combination of the side effects of treatment and attending hospital every day. Be prepared to rest when necessary during treatment. We would encourage you to try to carry on with all your normal activities as much as possible.

Bowel effects - Some of your bowel will be included in the treatment area as it is very close to the bladder, it can become inflamed and result in these specific side effects:

- Diarrhoea- loose motions or increased frequency of motions
- Abdominal bloating and discomfort
- Bleeding or mucus loss from the back passage
- Sensation of needing to empty your bowels even though nothing is there (tenesmus)
- Discomfort opening bowels

Bladder effects

- Discomfort/stinging on passing water
- Passing urine more often and more urgently

- Difficulty starting to pass urine and a slower flow of urine
- Getting up more at night to pass urine
- Bladder spasms
- Passing blood in urine

Occasional short term side effects:

Skin and hair effects

- The skin in the treated area (front and back) may become red and sore, but this varies from person to person. We recommend the use of simple moisturisers such as Diprobase or E45. You can wash the area gently using a mild un-perfumed soap. If you are uncertain about using your own creams on skin being treated with radiotherapy, please ask a member of the team as some creams can make your skin reaction worse.
- You may lose pubic hair in the treated area, but it will grow back once the treatment is complete.

Bladder effects

- There may be severe urinary symptoms which require the temporary use of a catheter.

Long term side effects:

Common long term side effects:

These late side effects are hard to predict and unfortunately may be permanent if they do occur.

Mild bowel effects

- Permanent change in bowel habit – your stools may be more loose, you may open your bowels more often or more urgently.
- Passing blood or mucus from the back passage may persist. There are treatments available if needed.
- There may be some foods which your bowels do not tolerate as well as before treatment.

Bladder effects

- Your bladder may shrink after radiotherapy and you may feel the urge to pass water more often or more urgently.

Sexual effects and fertility

- Men - Following a course of pelvic radiotherapy, erectile dysfunction is more common in men aged over 50. Medications may be prescribed and/or we can refer you to the erectile dysfunction clinic to discuss treatment options if needed.
- Women - Premenopausal women may experience menopause 3 to 4 months after pelvic radiotherapy completes. Vaginal narrowing and dryness may occur. The radiotherapy femcare team will discuss with you the use of vaginal dilators during radiotherapy to reduce vaginal narrowing.
- Fertility - Radiotherapy to the pelvic area can cause permanent infertility. If this is important to you, please discuss with your doctor.

Skin changes

- Long term the skin can look different in the treated area and feel tougher - pigment changes and the development of small blood vessels on the skin surface.

Rare long term side effects:

- There is an increased risk of fracture of the pelvic and sacral bones after radiotherapy, especially if you receive radiotherapy to the pelvis. These are usually hairline and treated with painkillers.
- Leg swelling called lymphedema occurs in a very small number of patients
- In the long term there may be a slightly increased risk of developing a new cancer caused by the treatment. Accurate information on this is not available and the benefits of the treatment far outweigh any potential risk in the future. If you are at all concerned then please speak to your medical team.
- Very rarely, the bladder may become poorly functioning, requiring the use of a catheter long term or surgery to remove the bladder.

Radiosensitisation (if applicable)

Bladder Carbogen and Nicotinamide (BCON) treatment and side effects (if applicable)

- **Carbogen:** This is a gas made up of 98% oxygen and 2% carbon dioxide which is given through a breathing mask while you are lying on the radiotherapy couch receiving treatment.
 - There may be slight discomfort with wearing a breathing mask and short term breathlessness occasionally after using the mask but this should not be severe.
- **Nicotinamide tablets** (also known as Niacinamide or nicotinic acid): This is a vitamin which helps increase blood flow in the tumour. The tablets only need to be taken on days when you receive radiotherapy, 1½ - 2 hours before the radiotherapy treatment.
 - Common side effects include nausea and less commonly headaches, dizziness and flushing. These effects may be reduced by taking the tablets with food. If you suffer from any of these side effects please let us know, we may suggest either reducing the dose or stopping the tablets.

Chemotherapy (if applicable)

- **Mitomycin and Fluorouracil (5FU)** - intravenous combination chemotherapy
- **Gemcitabine** - intravenous single agent chemotherapy
 - In general chemotherapy can cause tiredness, nausea and vomiting, diarrhea, increased risk of infections, bleeding or bruising, anemia, blood clots, skin reaction. More detailed information about specific chemotherapy side effects and practicalities will be provided if applicable.

Is there anything else I need to be aware of?

During the course of your treatment it may be necessary to:

- Admit you to hospital, for instance if you develop infection.
- Insert a urinary catheter if you develop urinary retention or suffer from significant urinary symptoms.

Are there any alternative options?

Your doctor will have discussed alternative options with you prior to planning for radiotherapy treatment. Suitable treatment options depend on the size of bladder cancer and how aggressive the cancer cells are.

In general, other possible alternatives include:

- Surgery to remove the bladder. This may not always be recommended.

What will happen if you decide not to have the treatment?

If you choose not to have any treatment, then the bladder cancer can continue to grow and may spread to other organs, causing you symptoms such as pain. The untreated cancer can eventually shorten your life expectancy.

Will there be any follow up appointments?

At the end of your treatment the radiographers will give you advice and contact numbers. The first follow up appointment will be 6 to 8 weeks after treatment. We will assess how you are following radiotherapy and to review side-effects from treatment. At this point, the short-term side-effects should be settling down. We will then discuss arranging further investigations to assess the response to your radiotherapy treatment.

Who should I contact if I have any other concerns?

The Radiotherapy Information and Support Team are available Monday to Friday, 8am to 5pm. Contact them on:

- **0114 226 5282**
- sth.rinfo@nhs.net

Urology Site Specialist Therapeutic Radiographers:

- **0114 226 5024**

For out of hours emergencies (after 5.00pm and at weekends):

- **0114 266 8345** or **0114 271 2733**

Ask to speak to the assessment unit nurse at Weston Park Hospital

You can also call your specialist nurse or consultant's secretary if it is not urgent.

For general hospital enquiries:

Patient Services Team:

- 0114 271 2400
- PST@sth.nhs.uk

Where can I find further information?

Weston Park Cancer Information and Support Centre	0114 553 3330
Rotherham Macmillan Cancer Information and Support Centre	01709 427 655
Doncaster Macmillan Information and Support Service	01302 796 853
Chesterfield Cancer Support Drop-in Centre	01246 516 406
Macmillan Cancer Support	0808 808 0000 www.macmillan.org.uk
Prostate Cancer UK	0800 074 8383
NHS Smokefree National Helpline	0300 123 1044

Signing the consent form

Before we are able to undertake any medical treatment, test or examination we must seek your consent first. For some procedures we do this by asking you to sign a written consent form. It is important you fully understand what the procedure involves before you give your consent. The information in this leaflet aims to provide as much information about the procedure to help you make this decision. If you need more information or are unsure about any aspect of the procedure or treatment proposed please do not hesitate to ask for more information. Some questions you should consider include:

- What are my options?
- What are the pros and cons of each option?
- Do I need more information or support to help make this decision?

Please do remember that you are entitled to change your mind at any point, even after the consent form has been signed. If you do change your mind we recommend you discuss this with your doctor.



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Alternative formats can be available on request. Email: sth.alternativeformats@nhs.net

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Consent Form 1

Patient agreement to: Radical radiotherapy treatment for bladder cancer

Name:
DoB:
Hosp. no. (Affix Patient Label here)
NHS no.

Responsible healthcare professional:

Name:
.....
Job title:
.....

Does this patient have any special requirements? (e.g. other language / other communication method)

Yes No

If Yes, details to be provided here:

Does this patient have an advanced decision to refuse treatment? (e.g. Jehovah's Witness form)

Yes No

If Yes, has the advanced decision been included within the consent discussions? Yes No

Statement of healthcare professional (to be filled in by healthcare professional with appropriate knowledge of proposed procedure, as specified in consent policy)

In particular, I have explained to the patient the:

1. Name of the proposed treatment or procedure (or course of treatment or procedures - include brief explanation if medical term is not clear):

The name of your treatment is radical radiotherapy for bladder cancer.

2. The intended benefits, for this patient, being to:

The aim of treatment is to cure you of bladder cancer or to achieve long term local control of bladder cancer.

3. I have also discussed:

- what the procedure is likely to involve
- the benefits and risks of any available alternative treatments
- the benefits and risks of no treatment

In particular, I have explained to and discussed with the patient the:

4. Recognised risks and/or complications for this particular procedure or treatment:

4.1 What are the known risks for this treatment or procedure? In particular the recognised significant, serious, frequently occurring or other risks this patient should be made aware of:

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4.2 Do any of the risks discussed carry a greater significance for this patient? For example, existing co-morbidities, patient's concern, patient's work, hobbies, driving or other.

Yes No

If Yes, details to be provided here;

.....
.....
.....

5. Are there any extra procedures which may become necessary during the treatment or procedure?

- blood transfusion
- other procedure/s (please specify)

.....

6. The following leaflet(s) has been provided: PIL4904, Issue Date: March 2021

Accompanying leaflet accepted by patient: Yes No

I have fully informed this patient about this procedure or treatment to the best of my ability and in a way in which I believe they can understand.

Patient refused information

(NB: If this patient has refused information ensure this is documented in the patients' medical records. Notify the GP of this and send the patient information leaflet to the GP with the letter in case the GP gets the opportunity to discuss this with the patient at a later date.)

Signed (Healthcare professional) **Date**

Name (PRINT) **Job title**

Professional Registration Number

Name:

DoB:

(Affix Patient Label here)

Hosp. no.

NHS no.

Statement of interpreter

Does this patient require an Interpreter? Yes No

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed (Interpreter)

Date

Name (PRINT)

Statement of patient (to be signed, printed and dated by the patient)

Please read this form and the accompanying leaflet carefully. The leaflet describes the benefits and risks of the proposed treatment or procedure and possible alternatives. If your treatment or procedure has been planned in advance, you should already have your own copy of the leaflet. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

.....

Signed (Patient)

Date

A witness should provide their signature if the patient is unable to sign but has indicated his or her consent.

Name (PRINT)

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions or concerns and consent for the procedure to go ahead.

Signed (Healthcare professional)	Date
Name (PRINT)	Job title
Professional Registration Number	

Withdrawing of consent to proceed with treatment or procedure (to be completed at any stage the patient withdraws consent to proceed with the treatment or procedure).

I, the patient, confirm that I have withdrawn consent and do not want to proceed with the treatment or procedure.

Signed (Patient)	Date
A witness should provide their signature if the patient is unable to sign but has indicated his or her withdrawal of consent.	
Name (PRINT)	

On behalf of the team treating the patient, I have confirmed with the patient that they have withdrawn consent and do not want to proceed with the treatment or procedure.

Signed (Healthcare professional)	Date
Name (PRINT)	Job title
Professional Registration Number	

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment or procedure you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoire to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the Department of Health's, *Reference guide to consent for examination or treatment*, for a comprehensive summary of the law on consent. Also available at

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653_1.pdf

Who can give consent

Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated, and therefore may sign this form (**Consent form 1**). If a child under the age of 16 has "sufficient understanding and intelligence to enable them to understand fully what is proposed", then they will be competent to give consent for themselves. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for themselves, someone with parental responsibility may do so on their behalf and a **separate form (Consent form 2)** is available for this purpose. Even where a child is able to give consent for themselves, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

Where an adult patient (18 or over) lacks capacity to give or withhold consent to treatment then **Consent form 4** should be completed.

When NOT to use this form

If the patient is 18 or over and is not legally competent to give consent, you should use **Consent form 4** (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:

- they are unable to comprehend and retain information material to the decision; and/or
- they are unable to weigh and use this information in coming to a decision.

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

Information

Information about what the procedure or treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure or treatment proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly.

Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the form or in the patient's notes.