CReST2

Colo**Re**ctal **S**tenting **T**rial **2** - Uncovered vs covered endoluminal stenting in the acute management of obstructing colorectal cancer in the palliative setting.

Patient Information Sheet

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An invitation to take part in a research study called CReST 2

*You are being invited to take part in a research study called **CReST2**. Before you decide whether you wish to take part in the **CReST2** study, we would like to explain why the research is being done and what it will involve for you. This information sheet provides you with a detailed description of the study so that you can think about whether you want to take part.*

- *Part 1 tells you the purpose of this study and what will happen to you if you take part.*
- *Part 2 gives you more detailed information about the conduct of the study.*

*Please take your time to think about whether you want to take part in the **CReST2** study, talk to your friends, family and your GP about the study if you wish and ask us if there is anything that is not clear or if you would like more information.*

Part 1

What is the purpose of the CReST2 study?

Stenting for patients with large bowel obstruction has high initial success rates, but is associated with a risk of complications from the stent at a later date. These complications include re-blockage of the bowel, migration of the stent and rarely perforation of the bowel. Therefore we are continuing to research ways of improving treatment and in the **CReST2** study we are comparing two types of stent design; uncovered and covered stents. Both types of stent are made of wire mesh but the covered stent has a fabric coating over the wire mesh.

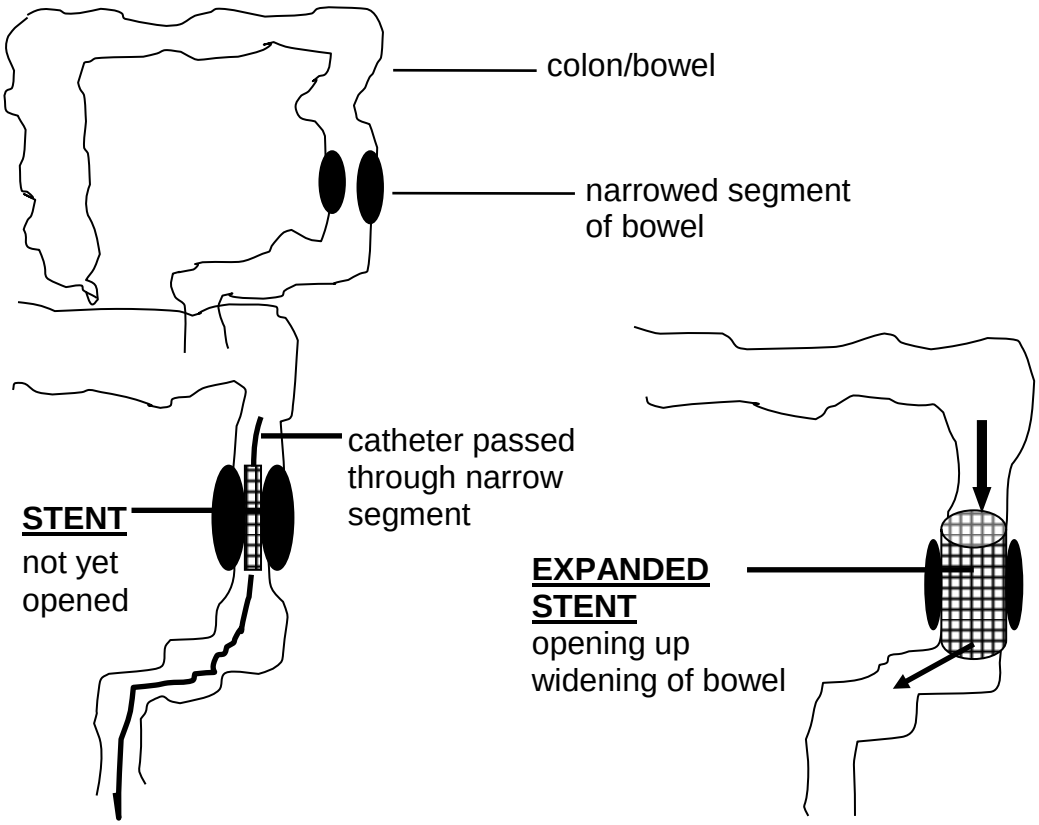
Why am I being invited to take part in CReST2?

Your doctor will have invited you to consider taking part in **CReST2** because you have bowel cancer that has caused an obstruction of your bowel that needs to be treated. The tests that have been performed show that the cancer cannot be cured by surgery and/or that you are not fit enough to undergo major surgery. Your doctor is not sure whether the best treatment for you is to insert an uncovered or a covered stent and so thinks that taking part in **CReST2** would be a good option to help find out which of these treatments is best. The **CReST2** study aims to include at least 350 people like you with large bowel obstructions caused by colon cancer from hospitals throughout the UK and elsewhere.

What are the treatments for large bowel obstruction?

Until recently, the standard treatment for patients with a blockage of the large bowel caused by cancer has been emergency surgery to relieve this obstruction. In some cases the ends of the bowel can be joined together but it is often the case that after this surgery the patient was left with a stoma (bringing one end of the bowel out onto the abdominal surface to allow passage of faeces into a bag), often permanently. In patients in whom the bowel cancer cannot be cured by surgery or in patients who are unfit to undergo surgery, stents are now recommended as standard treatment for relief of the obstruction. The stents are specifically designed metal mesh tubes, which if passed across the blockage in the bowel, act to open it up and thereby relieve the obstruction allowing faeces and flatus (wind) to pass normally. In the majority of patients this avoids surgery and the need for surgery and the need for a stoma.

The diagram shows what this means:



What does the standard treatment involve?

The standard treatment involves insertion of an uncovered **stent**. This is passed across the blockage in the bowel, acts to open it up and thereby relieve the obstruction allowing faeces and flatus (wind) to pass normally. Following the stent insertion you would continue to be followed up to check that the stent is still working properly.

What are the benefits of standard treatment (stenting)?

Stenting is the recommended treatment for patients such as yourself with a bowel obstruction caused by cancer. There are advantages of stenting compared to surgery. These include safer treatment, a shorter stay in hospital and less chance of a stoma (bag on the side to collect the bowel content).

What are the risks of standard treatment (stenting)?

There is a small risk of failure to place the stent due to technical difficulties. In this case, surgery will have been delayed and you will still need to undergo urgent surgery.

As with all procedures, complications of stenting can occur. Previous experience has shown a small risk of bowel perforation (making a hole in the bowel wall) whilst placing the stent. This would be treated by immediate surgery. There is a risk that the tumour grows into the stent and causes repeat blockage of the bowel. Migration of the stent (when the stent moves from its original site) has also been seen. This occurs following widening of the narrowed segment and the stent is usually passed with a bowel motion without causing any discomfort. Replacement of the stent is only necessary if recurrence of the blockage occurs.

The radiation dose received during stenting is similar to other X-ray treatment procedures (such as X-rays of the heart for coronary artery disease). The X-rays you may have as part of your treatment under the trial are the same as if you were not participating in the study. All X-rays carry with them some risk from the radiation dose. However there will be no additional radiation risk from you taking part in the trial and you are not likely to suffer any short or long term harmful effects from the radiation.

Do I have to take part?

No. Taking part in research is always voluntary. If you decide to take part you will be given this information sheet to keep, and will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason. If you decide not to take part, then you don't have to give a reason why and no-one will think badly of you for not wishing to take part. Your specialist will be happy to talk through alternative options.

What will happen to me if I agree to take part in CReST2?

To begin with, all patients will have been investigated with either a contrast CT (this is a scan which takes images of your body using x-rays) or a contrast enema (this is a fluid that is passed into the large bowel via the bottom and will show up on x-ray). This fluid then allows x-ray pictures to be taken to confirm the diagnosis of large bowel obstruction and to determine the exact site of the blockage. Other patients will have been investigated with a telescope examination of the bowel.

The surgeon/radiologist will go through the study information again and answer any questions you have. If you are willing to take part in the **CReST2** study you will be asked to sign a separate consent form. Your details will then be passed to the **CReST2** trial office at the University of Birmingham who will provide your randomly assigned allocated treatment.

The below table shows how you will progress through the **CReST2** trial:

1)	**Entry into trial (after signing a consent form).**
2)	**Randomly assigned treatment of a covered or an uncovered stent will be performed by a Radiologist/Endoscopist**.
3)	**Completion of Quality of Life Questionnaires at trial entry date, 30 days after you have had your stent, 3 months, 6 months, 12 months, 18 months and 24 months after you entered the trial.**

If you decide to take part in **CReST2** you will have the obstruction treated by either:

- **i)** Insertion of an uncovered stent
- **ii)** Insertion of a covered stent.

Which of these treatments would I receive?

So that we can find out which treatment is best, each person is put into a treatment group randomly (like tossing a coin). You have an equal chance of being allocated to the uncovered or covered stent groups.

It is important to realise that the treatment you receive will be decided by chance using a computer programme. The reason for having your treatment decided by chance is that it allows a fair comparison of the different treatments used in the study so that at the end of CReST2 we can decide which is best. Neither you nor your doctor are able to influence which treatment you receive.

Dividing people into treatment groups in this way is what is called a 'randomised clinical trial' and it is the standard and most reliable way of comparing different treatments.

Stent Insertion

For both allocated treatments, stent placement will be carried out in the X-ray suite or endoscopy unit. When a stent is inserted you will be given some sedation (this makes you relaxed and probably a little sleepy). You will be positioned on your left side and under x-ray guidance a specially designed guidewire will be passed through the blockage in the bowel. This wire acts as a guide so that the stent can be placed in the correct position in the large bowel. In some cases a flexible telescope (sigmoidoscopy) might be needed to locate the narrowed passage through the bowel.

When the stent is in the right place it is released and immediately expands to widen the narrowing of the bowel. When the stent expands there is usually a sudden passage of wind and sometimes liquid faeces, this is normal and is nothing to worry about.

After stenting you will be returned to the ward and may be discharged home the following day, as long as your bowels are opening normally. If you are not going to have surgery the stent will remain in place and surgery will be avoided altogether.

Would taking part in CReST2 involve extra clinic visits or investigations?

Whether or not you take part in the **CReST2** study, your progress will be followed up regularly.

As a participant in the **CReST2** study, you will be followed up for a period of two years. You will be reviewed in the outpatient clinic at four weeks after discharge, then every three months for the first year. You will then be seen every six months for a further year.

As part of the **CReST2** study, we will ask you to complete questionnaires to tell us how healthy you feel and how well your bowels work. **However, you would not be required to attend any additional clinics** and the questionnaires will be posted to your home if you are not due to attend a follow up appointment.

You may on occasion be contacted by letter, telephone or e-mail to remind you to complete the questionnaires or to be asked the questions over the telephone.

What are the possible benefits from taking part in CReST2?

It is believed that covered stents may be more effective than uncovered stents leading to less risk of complications and a better Quality of Life. Covered stents may reduce the risk of tumour ingrowth into the stent so have less chance of re-blockage. If this is the case, there would be less chance of needing further interventions such as repeat stent insertion or surgery). However, we cannot be sure in advance that covered stents will have all or any of these benefits – that is the reason for doing this trial. We believe that participation in **CReST2** will provide you with the best available treatment for your cancer. The main benefit from **CReST2** will be that the information gained from the study will help doctors in the treatment of patients in a similar condition to yours in the future.

Part 2

What if new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, your research doctor will discuss how this affects your care and your participation in the **CReST2** study. Your research doctor might consider that you should continue in the study or withdraw. Either way, he/she will explain the reasons and arrange for your care to continue. If you decide to continue in the study he may ask you to sign an updated consent form. If the study is stopped for any other reason, your doctor would, again, tell you and arrange your continuing care.

What will happen if I don't want to carry on with the study?

You can decide not to continue with study treatment at any time but, if you do, we would still like to follow up your progress and your data would remain on file and be included in the final study analysis unless you request that they should not be.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If the harm is due to someone's negligence, then you may have grounds for a legal action but you may have to pay for this. Whether or not you take part in the study, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you. If you do have any concerns or wish to complain, the first point of contact would be the local Patient Advice and Liaison Services (PALs) office at:

Trust/Hospital Name:.....

Location:.....

Tel No:.....**Position:**.....

Taking part in the study would not affect your legal rights.

Will my taking part be kept confidential?

If you decide to take part in **CReST2**, all information collected about you during the course of the trial will be kept strictly confidential in the same way as all of your other medical records. Information about your disease and progress will be sent by your doctors to the **CReST2** Study Office at the University of Birmingham Clinical Trials Unit (BCTU), on paper and electronically, where it will be securely stored under the provisions of the 1998 Data Protection Act. This will include a signed copy of your consent form. Your GP, and the other doctors involved in your clinical care, will be notified of your participation in the **CReST2** trial and kept informed of your progress. We may use national NHS records to track your progress, but otherwise all information about you and your treatment will remain confidential.

With your permission, your relevant medical records may be inspected by authorised individuals from the University of Birmingham Clinical Trials Unit (BCTU). They may also be looked at by the NHS Trust, the trial Sponsor or the regulatory authorities to check that the study is being carried out correctly.

What will happen to the results of the study?

Once the trial has finished we will publish the results in a medical journal so that others can benefit. We will also publicise the results on the trial's website www.birmingham.ac.uk/crest2. No individual patients will be identified in any publications. A copy of the published results of the trial will be sent to all patients who have participated in **CReST2**. In line with clinical trial guidelines, at the end of the study, the data will need to be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made. Should you withdraw consent for your data to be used, it will be confidentially destroyed.

Who is organising and funding the research?

The **CReST2** study was developed by the National Cancer Research Institute's Colorectal Cancer Clinical Studies Group, and is funded by the Health Technology Assessment Programme, which is part of the National Institute for Health Research. The study is coordinated by the Birmingham Clinical Trials Unit at the University of Birmingham. The research has been reviewed and approved by all of these organisations, and also by an independent NHS Multi-centre Research Ethics Committee. There is no involvement of any companies other than providing stents at reduced price.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Tyne and Wear South Research Ethics Committee.

Where can I get further information?

If you have any further questions about your disease or clinical trials, please discuss them with your doctor:

[Local trial team contact details]

You may also find it helpful to contact:

Macmillan Cancer Support (www.macmillan.org.uk; 0808 808 0000)
NHS Choices (http://www.nhs.uk/Conditions/Clinical-trials)

The **CReST2** study coordinating centre is located at the University of Birmingham Clinical Trials Unit, Institute of Applied Health Research, College of Medical and Dental Sciences, University of Birmingham, Birmingham, B15 2TT.
Web address: www.bctu.bham.ac.uk
e-mail: crest2@trials.bham.ac.uk

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