

# Singing the praises of breakthrough in bladder cancer treatment

More than 10,000 people are diagnosed with bladder cancer each year in the UK. Many of these suffer a recurrence of the disease if standard treatments fail and can often be left facing major surgery as their only option. But the Cancer Research Network is now supporting a study which is trialling a pioneering new treatment that could give patients an alternative.

Bladder cancer is one of the most common cancers in the UK and patients suffering with this high risk disease have limited therapy options. Despite this, there are few trials in this area because they are complex and difficult to run. The standard treatment is to put BCG (the vaccine for tuberculosis) into the bladder using a catheter - but it is only 50 per cent effective. If this fails, patients face a major operation to remove the bladder - often when they have other medical problems making them unfit for surgery. Plus, it usually means living with a urostomy bag for the rest of their life.

But with the help of the Clinical Research Network, a new treatment called thermo-chemotherapy is already providing patients in Middlesbrough with options they didn't previously have. The HYMN study, developed through the National Cancer Research Institute and funded by Cancer Research UK, is trialling this innovative treatment. It is available to patients with an aggressive form of the cancer that has a high risk of invading deeper into the body and spreading beyond.

Jo Cresswell is one of the principal investigators for the HYMN study and a Consultant Urological Surgeon at The James Cook University Hospital, part of South Tees Hospitals NHS Foundation Trust. She explains how thermo-chemotherapy works:

"We put a chemical wash into the bladder and then heat the bladder to 42°C using a special catheter with small

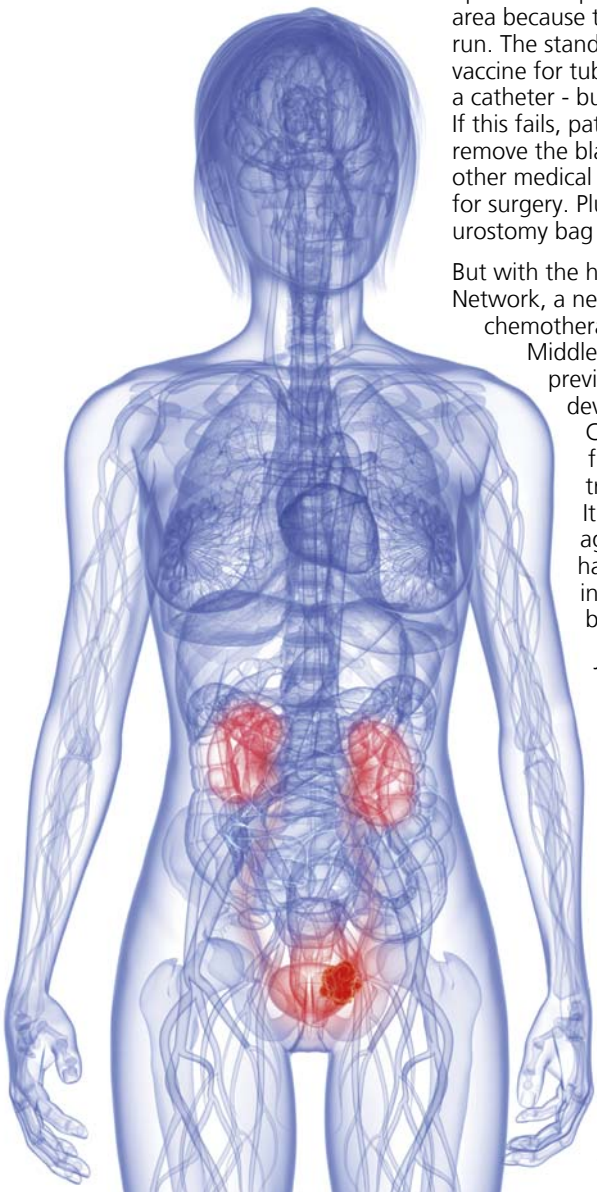
electrodes; this catheter has three channels which are inserted into the bladder. One puts the chemotherapy drug mitomycin C in, another removes it, and the final one heats the bladder via radio frequency to increase the take up of the drug."

This promising new treatment appears to improve the absorption of the chemotherapy - killing the cancerous cells. It has already been trialled in Europe where studies show over half of those treated in this way remain disease free after two years.

**"it would have been impossible to run the study without Network support"**

Patients who do not respond to the standard NHS treatment are invited to take part in the trial. They agree up front to be randomised to either continue with the BCG washes or begin thermo-chemotherapy. The HYMN study has reached its target to get 10 sites out of 20 open for recruitment in its first year and so far 30 patients have joined the trial. Eight of these have been recruited at the Middlesbrough site and four of those have received thermo-chemotherapy treatment.

*Improving the odds. The HYMN study is providing bladder cancer patients with an alternative treatment option*



This is good news for Jo Cresswell and her team who are motivated by the welfare of their patients. Their enthusiasm and commitment to the study meant that the first patient was recruited within a day of it opening. She points out how valuable this trial is to patients:

“This trial has been needed for a while and it has been frustrating not to be able to help some patients. Despite the fact that it’s a randomised controlled trial and patients may or may not receive the new treatment, they are still keen to participate because they don’t have many other choices if the standard treatment fails. They would rather a 50 per cent chance of getting the new treatment”.

But trials like this one are difficult to set up. Jo Cresswell explains:

“Surgical trials are infrequent because they are difficult to deliver as they are labour intensive and require expensive equipment. The Synergo system© had to be installed at Middlesbrough on loan as this provides the key heat-generating system essential to the treatment.

“Plus a study like this takes up a lot of clinical time, as each patient requires one treatment per week for six weeks, taking one hour of a clinical nurse and doctor’s time – that’s six hours per patient. And if the treatment is effective, booster treatments are given thereafter.”

Consequently, the Network support for this trial has been crucial. Jo Cresswell continues:

“We can’t deliver treatments in the context of normal clinics so it would have been impossible to run without Network support. Our Comprehensive Local Research Network covered the cost of the medical and nursing sessions, that is, a nurse and doctor to deliver the treatment. And the Cancer Research Network was a massive support in recruiting and counselling new patients.”



**HYMN study team.** Lynn Mudd, Lorna Braim and Tracey Whittingham with the thermo-therapy machine

Jo Cresswell is emphatic that not only would it have been impossible to run the study in Middlesbrough without the Network, but also without the very motivated study team.

Paul Caster who is taking part in the trial was diagnosed with cancer in October 2009. After failing to respond to standard treatments, he was facing the decision to remove his bladder when he was told about the HYMN trial. He talks about his experience:

“I didn’t want to take the next step, so when I was told about this trial I was keen to be involved to avoid having my bladder removed. My illness is very embarrassing and a lot of people find it difficult to talk about, but the study team, in particular Sister Lynn Mudd, have made me feel totally relaxed throughout the treatment. I have now had the full course and I’m awaiting the results of my biopsies – I’m hoping for good results!”

He goes on to explain why this form of cancer is so devastating to patients and why the study is so important:

“The cancer and treatment is a huge imposition on my life. My company have

been very understanding but it is still difficult to manage, and it affects my partner too. If the cancer spreads we will deal with the consequences together but I don’t know how I’m going to feel; my life will change forever. This new treatment has given me hope and if it’s successful it will be better than winning the lottery. Put simply, I will get my life back.”

It is hoped that if this multicentre trial proves that thermo-chemotherapy works it will eventually be taken up as a standard treatment within the NHS - to the benefit of all patients.

Jo Cresswell reflects on the Network impact on the HYMN study;

“The Network was supportive, flexible and receptive to new ideas, they helped me work through the regulatory steps and necessary paperwork.” She adds, “the study wouldn’t have run without the Network”.

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