

Drug trial success could reduce the risk of bladder cancer recurring by a third

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A MAJOR bladder cancer trial, funded by Cancer Research UK, has shown that adding two commonly used chemotherapy drugs to traditional radiotherapy can reduce the chance of a patient's tumour coming back by a third.

The trial - led by scientists at the University of Birmingham, and the Institute of Cancer Research (ICR) - is the largest of its kind in bladder cancer in the world. Its success could mean fewer patients with invasive bladder cancer will need radical surgery to completely remove their bladder.

The results will be presented at the American Society for Therapeutic Radiology and Oncology (ASTRO) annual conference next Monday (1st November 2010)*.

Professor Nick James, from the University of Birmingham, who led the study with Dr Robert Huddart from the ICR, said: "These trial results are hugely promising, with a significant reduction in the risk of the cancer returning when compared to radiotherapy alone. When we looked at the risk of potentially lethal invasive disease returning the improvement was even more marked.

After two years of follow up the results showed a tumour relapse rate of 33 per cent for patients receiving chemotherapy in addition to radiotherapy -known as chemoradiotherapy - compared to 46 per cent for radiotherapy alone. The reduction in relapse of the most severe type of tumour was even more marked at 18 per cent versus 32 per cent percent.

He added: "Importantly, both chemotherapies used in this trial are cheap widely available drugs that are commonly used in cancer treatment already. This makes their use much more practical.

"Having surgery to remove the bladder is a major operation that can seriously impact a patient's quality of life. We have shown that adding chemotherapy to radiotherapy reduces the risk of the most severe type of tumour recurring by nearly half. Hopefully these trial results will mean more bladder cancer patients are given the opportunity to avoid surgery and preserve their bladder function."

Patients diagnosed with invasive bladder cancer are usually offered either radiotherapy alone - which carries a 40 to 50 per cent chance of the cancer coming back - or surgery to completely remove the bladder.

But giving the two chemotherapy drugs – 5FU and Mitomycin C – at the same time as the radiotherapy helped make the cancer cells more sensitive to it, boosting the effectiveness of the treatment.

The new approach could lead to fewer invasive bladder cancer patients being referred for surgery and may provide a lifeline for those too old or weak to survive the operation.

Each year in the UK around 10,300 people are diagnosed with bladder cancer. It is responsible for more than 4,900 deaths per year, primarily in older people, and is the fourth most common cancer in men.

Kate Law, director of clinical research at Cancer Research UK, said: "The results of this promising trial offer patients a potentially effective option for those who want to avoid having their bladder removed.

"This is particularly important since eight out of ten cases of bladder cancer occur in patients over 65, meaning many patients are unsuitable for surgery due to their age or other pre-existing health conditions.

"This trial demonstrates that efforts to maximise the effectiveness of radiotherapy and chemotherapies are vital. These treatments remain a crucial part of the fight against the disease."

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Notes to editor

* The 52nd American Society for Therapeutic Radiology and Oncology (ASTRO) annual meeting is taking place in San Diego, USA, from 31 October - 4 November 2010.

See: www.astro.org

The BC2001 Trial

The BC2001 trial was a randomized multi-centre trial looking at radiotherapy with or without chemotherapy for people with invasive bladder cancer.

The UK-wide trial involved 458 patients. It investigated the addition of chemotherapy to radiotherapy (known as chemoradiotherapy), as well as two different ways of giving radiotherapy. 360 patients were included in the study that looked at chemoradiotherapy, making it the largest study of this type of treatment of bladder cancer in the world to date.

All of these 360 patients received radiotherapy and half were randomly chosen to receive the chemotherapy drugs 5 Fluorouracil (5-FU) and Mitomycin C alongside their radiotherapy.

This work was supported by Cancer Research UK (CRUK/01/004) and the trial was co-ordinated by the Cancer Research Clinical Trials Unit (CRCTU) at the University of Birmingham (C547/A2606; C547/A6845; C9764/A9904) and the Cancer Research UK funded Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU) (C1491/A9895).

For further information visit: <http://www.cancerhelp.org.uk/trials/a-trial-looking-at-radiotherapy-with-or-without-chemotherapy-for-people-with-bladder-cancer>

About bladder cancer

- Bladder cancer is the seventh most common cancer in the UK.
- Each year in the UK around 10,300 people are diagnosed with bladder cancer.
- Bladder cancer is the fourth most common cancer in UK men, with more than 7,300 new cases each year. There are more than twice as many cases in men as in women.
- Each year in the UK, around 4,900 people die from bladder cancer.
- Almost nine in ten deaths from bladder cancer are in people over 65.
- Since peaking in the early 1990s, the bladder cancer death rate in men has decreased by more than a third.
- Invasive bladder cancer means that the cancer cells have spread beyond the inner lining and into the muscle layer of the bladder.
- For more information about bladder cancer visit CancerHelp UK: <http://www.cancerhelp.org.uk/type/bladder-cancer/index.htm>

About Cancer Research UK

- Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research
- The charity's groundbreaking work into the prevention, diagnosis and treatment of cancer has helped save millions of lives. This work is funded entirely by the public.
- Cancer Research UK has been at the heart of the progress that has already seen survival rates double in the last forty years.
- Cancer Research UK supports research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses.
- Together with its partners and supporters, Cancer Research UK's vision is to beat cancer.

For further information about Cancer Research UK's work or to find out how to support the charity, please call 020 7121 6699 or visit www.cancerresearchuk.org

The University of Birmingham's track record in cancer clinical trials

- The University of Birmingham has one of the largest clinical trials clusters in the UK, with more than 25 years experience in delivering clinical trials, translating world-class cancer research into improved patient survival.
- From identifying quicker and better ways to diagnose cancer to harnessing viruses in the fight against cancer, the University of Birmingham's cancer experts are committed to finding ways to individualise cancer treatments and reduce the toxicity of the treatment, so that life after cancer is improved.
- The Cancer Research UK Clinical Trials Unit (CRCTU) at the University of Birmingham stands comfortably between the Pan Birmingham network of hospitals, that serve a population of more than 5,000,000 people, and a large basic science research group of more than 200 researchers situated at the University's School of Cancer Sciences. The CRCTU is one of three clinical trials units within the University the other two being the Birmingham Clinical Trials Unit (BCTU) and the Primary Care Clinical Research and Trials Unit (PC-CRTU)
- The CRCTU was established in 1983 and in 2007 had live funding at around £20m. In the past three years CRCTU staff have contributed to more than 140 clinical trials, acting as the coordinating centre for 58, with more than 39,000 patients participating.
- The West Midlands has the largest concentration of clinical trials activity in Europe, with the ethnically diverse population of the region being a significant attraction to companies who need to recruit such populations onto trials.

The Institute of Cancer Research (ICR)

- The ICR is Europe's leading cancer research centre
- The ICR has been ranked the UK's top academic research centre, based on the results of the Higher Education Funding Council's Research Assessment Exercise
- The ICR works closely with partner The Royal Marsden NHS Foundation Trust to ensure patients immediately benefit from new research. Together the two organisations form the largest comprehensive cancer centre in Europe
- The ICR has charitable status and relies on voluntary income, spending 90 pence in every pound of total income directly on research
- As a college of the University of London, the ICR also provides postgraduate higher education of international distinction
- Over its 100-year history, the ICR's achievements include identifying the potential link between smoking and lung cancer which was subsequently confirmed, discovering that DNA damage is the basic cause of cancer and isolating more cancer-related genes than any other organisation in the world
- The ICR-CTSU is an NCRI accredited and UKCRC registered trials unit which was established in the 1980s. Its main objective is to design, initiate, conduct and analyse national and international randomised clinical trials of cancer treatment which will directly influence routine clinical practice within the National Health Service and worldwide.
- ICR-CTSU has an established portfolio of phase III trials of systemic and radiological therapies in breast, urological and head and neck cancers and in addition has an emerging portfolio of peri-operative and surgical trials, as well as several phase II trials in rare tumour types.
- Over 2,000 UK and international patients enter ICR-CTSU trials annually and over 20,000 patients are currently in active follow up. We work with over 100 NHS Trusts in the UK.

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