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**Randomised Controlled Trial**

**People**

**LESS CHEMOTHERAPY BETTER FOR OLDER OR FRAIL PATIENTS WITH ADVANCED STOMACH AND OESOPHAGEAL CANCERS**

Less chemotherapy is as effective at controlling disease for elderly or frail patients with advanced cancer of the stomach or oesophagus (food pipe), and leads to fewer side effects such as diarrhoea and lethargy. These are the results of a Cancer Research UK funded study, presented prior to the ASCO conference today (Wednesday).

Results from the GO2 trial could change the standard of care for patients who can’t have full dose chemotherapy due to their age, frailty or medical fitness.

The study, which ran at hospitals all over the UK, coordinated from the University of Leeds, involved 514 people with stomach or oesophageal cancer. Their average age was 76 and the oldest was 96 years old. All were either frail, elderly or medically unfit, and for those reasons would be unlikely to tolerate full-strength treatment, which involves three chemotherapy drugs.

Patients went through a careful medical assessment, then went onto chemotherapy with just two drugs* and were allocated at random to receive them at either full-strength, medium-dose or low-dose. They were then carefully monitored to see how well the cancer was controlled, whether they had symptoms and side-effects, whether they felt their treatment was worthwhile, and what overall effect it had on their quality of life.

The researchers reported that the medium and lower doses of chemotherapy were as effective as the full-strength dose for controlling the cancer. But when the researchers looked at the overall effect of treatment, including quality of life, they reported that it was the lowest dose treatment that came out best.**

Around 15,800 people in the UK are diagnosed with stomach and oesophageal cancers every year***. Almost half (45%) of these people are 75 and over****. By 2035, this proportion is projected to rise to 55%*****, because of the UK’s ageing population. This study, is one of few phase III trials in the country that seek to address how to best care for and treat this increasing population of elderly or frail cancer patients.

These findings also open up the possibility of more older and frail patients being able to take part in clinical trials.
Professor Charles Swanton, Cancer Research UK’s chief clinician, said: “These valuable results reduce fears that giving a lower dose chemotherapy regimen is inferior and could make a huge difference for patients with stomach or oesophageal cancer who can’t tolerate intensive courses of treatment.

“Older or frail patients are often not considered for new drug trials or standard of care therapy as they’re less able to tolerate combination chemotherapy. These trials are critical to provide much needed evidence on the effectiveness of new therapies and combination approaches, helping us develop new treatments for this growing group of patients.”

The researchers also assessed whether there were differences for the patients in the study who were under 75, or less frail, who might be expected to benefit from stronger treatment; but will be reporting that the lowest dose treatment gave the best results for them as well.

Professor Matt Seymour, co-chief investigator at the University of Leeds and Leeds Teaching Hospitals NHS Trust said: “When we’re treating people who are elderly or frail, we are especially conscious that treatment can have harmful as well as beneficial effects. Doctors often prescribe reduced doses of drugs, or sometimes no chemotherapy at all, based on their clinical experience, but until now there has been little hard evidence to help them in those decisions. Our results provide that evidence, so doctors can confidently give people a lower dose of chemotherapy, sparing them side effects without worrying that it’s compromising their chance of survival.

“We hope this approach can be applied in other disease types so that more work can be done to improve both survival and quality of life for elderly and frail patients.”

Liz Chipchase, from Cambridge, was diagnosed with oesophageal cancer in 2017 at 69 years old. She had two non-invasive surgeries under sedation to remove the cancerous cells and didn’t require any additional treatment.

She said: “When I was diagnosed with oesophageal cancer, I was lucky that it was caught early enough that I didn’t need chemotherapy. I was offered the choice between two different surgeries, giving me the opportunity to select the treatment I thought was best for me.

“Trials like this are important to empower people with choices that give them control over how they’re treated – something I was fortunate to have. Any research that can help improve the quality of life for other patients is essential, so it’s great to see results like these doing exactly that.”

Dr Peter Hall, co-chief investigator from the Cancer Research UK Edinburgh Centre, said: “Increasingly we’re realising it’s not just age that affects how well someone can tolerate
their treatment and we need to do more work to understand how other conditions or aspects of frailty might play a role.

“We should now look beyond chemotherapies, at some of the newer targeted therapies or immunotherapies to understand how we can tailor different treatments to patients based on their individual circumstance.”

ENDS

For media enquiries contact Carl Alexander in the Cancer Research UK press office on 020 3469 8882 or, out of hours, on 07050 264 059.

Notes to editor:

* The chemotherapy drugs used in this study were oxaliplatin (an intravenous infusion given at the hospital once every three weeks) and capecitabine (tablets, taken at home twice daily)

**The study assessed the effects of treatment on quality of life, as well as survival using a measure called Overall Treatment Utility (OTU). This measure was developed by the researchers as part of a previous Cancer Research UK-funded trial, and takes into account: clinical response, toxicity, adverse events, quality of life and the patients' own reported acceptability of the treatment.

***Based on the average number of new cases of oesophageal (C15) and stomach (C16) cancer diagnosed in the UK in 2014-2016.


*****One-year age standardised net cancer survival by stage at diagnosis for oesophageal (IC10 C15) and stomach (ICD10 C16) cancer in adults (15-99 years), diagnosed in England between 2012-2016 and followed up to 2017.

Source: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/datasets/cancersurvivalratescancersurvivalinenglandadultsdiagnosed

For more information on Cancer Research UK’s policies on treating and caring for an ageing population, see here: https://www.cancerresearchuk.org/about-us/we-develop-policy/our-policy-on-access-to-cancer-treatments/treating-and-caring-for-an-ageing-population

About Cancer Research UK

- Cancer Research UK is the world’s leading cancer charity dedicated to saving lives through research.
- Cancer Research UK’s pioneering work into the prevention, diagnosis and treatment of cancer has helped save millions of lives.
• Cancer Research UK receives no funding from the UK government for its life-saving research. Every step it makes towards beating cancer relies on vital donations from the public.

• Cancer Research UK has been at the heart of the progress that has already seen survival in the UK double in the last 40 years.

• Today, 2 in 4 people survive their cancer for at least 10 years. Cancer Research UK’s ambition is to accelerate progress so that by 2034, 3 in 4 people will survive their cancer for at least 10 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 bring forward the day when all cancers are cured.

For further information about Cancer Research UK’s work or to find out how to support the charity, please call 0300 123 1022 or visit www.cancerresearchuk.org. Follow us on Twitter and Facebook.