**Background for Cytosponge Project**

**BEST3 Study information**

A recent Cancer Research UK funded medical trial **picked up 10 times more** **cases** of Barrett’s oesophagus, a pre-cancerous condition, than the GP’s usual first course of action.

The BEST3 trial involved more than 13,000 people and included research through GP practices which was facilitated by the Cambridgeshire and Peterborough Clinical Commissioning Group.

It used the ‘heartburn sponge’ (or Cytosponge and special lab test) developed by Professor Rebecca Fitzgerald, a Heartburn Cancer UK trustee, and her University of Cambridge and Addenbrooke’s Hospital teams.

The trial also identified early cancer in some patients.

**One person particularly thankful for the sponge test is 71-year-old Liz Chipchase**

Liz Chipchase joined the BEST3 medical trial to help out. She’d been treated for acid reflux/heartburn for 40 years but didn’t expect any issues to show up. The results of the sponge test revealed she, in fact, had oesophageal cancer. [[See the attached case study for more of Liz’s story.](https://drive.google.com/file/d/1jzKYyEGJwdtK_G3FPPMLPlPkvwMqQrW0/view?usp=sharing)]

Fortunately - she feels ‘completely well thanks’ to the sponge test trial - it was found at an early stage and was treatable.

Liz was one of the lucky ones. Because oesophageal cancer is often found late, is more usually fatal. Only 17% of people diagnosed with it live for a further five years or more after diagnosis.

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| **How the Heartburn Sponge Test works*** Patients are invited to have the test at the mobile unit when it’s brought to, or near, a GP surgery
* The nurse-led unit is being funded through a partnership between Heartburn Cancer UK (the charity that promotes awareness and champions early diagnosis), the University of Cambridge (which created the Cytosponge), Project DELTA (which is funded by Innovate UK to roll out the new technology as a routine procedure in GP practices and hospitals, in partnership with Medtronic who makes the device, and Cyted whose laboratories perform the diagnostic test) and other vital supporters
* People invited for the test by GPs will be over 50 and will have used medication to reduce stomach acid (PPIs - proton pump inhibitors) for some time
* A limited number of people can also self-refer for the test by phoning 01223 761 085 or emailing Irene.Debiram1@nhs.net These are likely to be over 40, regular users of over-the-counter or off-the-shelf reflux, heartburn or indigestion medications (such as Gaviscon, Rennie and Nexium) and who are not having any other medical investigations for these symptoms
* With some water, they will swallow a small ‘pill’, which is about the size of a large vitamin tablet. The capsule is attached to a string which will be used to retrieve the device
* The pill-on-the-string will sit in the stomach for five to seven minutes allowing the capsule to dissolve, releasing a small sponge
* The sponge is then retrieved using the string, catching cells on the way back up
* The retrieval will only take one or two seconds
* The whole process takes less than 10 minutes and is much easier, cheaper and less invasive than an endoscopy performed in a hospital, which is the normal way the NHS checks for these issues
* The collected cells will be sent to the Cyted lab to be checked using an advanced artificial intelligence-based diagnostic test developed by the University of Cambridge
* Only patients with something unusual detected by the sponge test will then be referred for an endoscopy by their GP
* The test will make sure people who need it can receive regular checks or endoscopy treatment to prevent cancer so that anything worrying is detected at an earlier stage
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**The Heartburn Sponge Test, using the Cytosponge, in pictures**\*

**Step 1: swallow a small pill on a string**



**Step 2: wait for 5 to 7 minutes**



**Step 3: pull it back in seconds**

With some water, the patient swallows a capsule attached to a thread containing the Cytosponge.

The capsule dissolves in the stomach and the Cytosponge expands. This takes between five and seven minutes.

A nurse pulls on the string attached to the Cytosponge and brings it back, along with some cells. This process takes one to two seconds.

\*Images courtesy of UCL Health Creatives. [Download the originals here.](https://drive.google.com/drive/folders/1qMJBlX2fPCkq0OH3WReJPgz1lDIaOn7C?usp=sharing)

**Main features and findings of the Cytosponge medical trial (BEST3 trial)**

* The ‘sponge on a string’ pill test identified ten times more people with Barrett’s oesophagus than the usual GP route (where most people were given medication and not referred for an endoscopy)
* The test can also pick up abnormal cells and potentially early-stage cancer
* The research was carried out by Professor Rebecca Fitzgerald, who is a Heartburn Cancer UK trustee, and her team from the University of Cambridge, and was funded by a grant from the Medical Research Council (MRC) and Cancer Research UK
* The trial involved 13,000 people (around 1,600 of whom received Cytosponge testing) and was a multicentre, pragmatic, randomised controlled trial run across 109 GP clinics in England
* Patients involved were 50 or older, had been taking acid-suppressants for symptoms of gastro-oesophageal reflux for more than six months, and had not undergone an endoscopy procedure within the past five years
* Half of the group were offered the sponge test. Half were in the standard care group
* The team compared how many people in each group were diagnosed with Barrett’s oesophagus. They also looked at whether cancers diagnosed from the Cytosponge test were at an earlier stage than those diagnosed in standard care
* The key finding was that around 10x more patients with Barrett’s oesophagus were diagnosed with Cytosponge compared with the standard GP practice
* Of the 131 people diagnosed with Barrett’s oesophagus and/or early cancer, nine people with early cancer benefitted from treatment as an outpatient via endoscopy.

**Useful facts and figures about oesophageal cancer and Barrett’s oesophagus**

* Each year, up to 40% of the adult population in the UK is thought to experience dyspepsia, which is pain or discomfort in the upper gut that covers indigestion, heartburn, acid reflux, regurgitation and sickness/nausea
* One-off issues are unlikely to signal a problem but having regular bouts of heartburn, or other similar conditions, can be a sign of cancer or a pre-cancerous condition called Barrett’s oesophagus, which considered the most important risk factor for oesophageal adenocarcinoma (oesophageal AC), the most common cancer of the food pipe (oesophagus) in the UK
* People who have regular heartburn are often unaware that they may have Barrett’s oesophagus. Those who do know will be offered regular checks
* Barrett's oesophagus can increase your risk of developing the most common cancer of the oesophagus (oesophageal adenocarcinoma), although the risk is still small. Many people with Barrett’s oesophagus do not develop cancer
* Between 3 and 13 people out of 100 (between 3 and 13%) with Barrett’s oesophagus in the UK will develop oesophageal AC, the most common cancer of the oesophagus, in their lifetime
* Each year, less than 1 in 100 people with Barrett’s (less than 1%) develop oesophageal adenocarcinoma. The risk of developing oesophageal cancer is higher if you have more severe cell changes (high-grade dysplasia)
* 8,000 people will die from oesophageal cancer each year in the UK
* About 22 people die each day of oesophageal cancer in the UK
* Overall, oesophageal cancer is the seventh most common cause of cancer death in the UK. In males in the UK, oesophageal cancer is the 4th most common cause of cancer deaths
* The UK has the worst survival figures in Europe for oesophageal cancer
* Oesophageal cancer rates in men have risen by 56% since the early 1970s. In women, they have increased by 14%

**Partnership working behind the mobile Heartburn Sponge Test unit**

The mobile unit has only been made possible through the support and funding of generous partners, donors and supporters.

They include:

* [Heartburn Cancer UK (HCUK)](https://www.heartburncanceruk.org/), which promotes awareness and champions early oesophageal cancer diagnosis
* Innovate UK funded [Project DELTA](https://www.deltaproject.org/), which is are rolling out the new technology as a routine procedure in GP practices and hospitals
* [Medtronic](https://www.medtronic.com/uk-en/index.html), which is providing the Cytosponges for Project DELTA and the mobile unit
* Heartburn Cancer UK trustee, [Professor Rebecca Fitzgerald](https://www.mrc-cu.cam.ac.uk/research/rebecca-fitzgerald), and her team from The [University of Cambridge](https://www.cam.ac.uk/) and [Addenbrooke’s Hospita](https://www.cuh.nhs.uk/about-us/our-hospitals/)l, who have developed the Cytosponge and associated laboratory test
* [Cancer Research UK](https://www.cancerresearchuk.org/), the [NIHR Cambridge Biomedical Research Centre](https://cambridgebrc.nihr.ac.uk/) and the [Medical Research Council](https://mrc.ukri.org/) (MRC) who funded and supported the trials to date, which proved the effectiveness of the sponge test
* [Cyted Ltd](https://cyted.ai/), which is a spin-out company from the University of Cambridge and provides the laboratory diagnostic testing for Cytosponge
* [Cambridgeshire and Peterborough Clinical Commissioning Group](https://www.cambridgeshireandpeterboroughccg.nhs.uk/), which worked with GP practices in the area to facilitate research that laid the foundations for the Heartburn Sponge Test unit
* [The Mid and South Essex Health and Care Partnership (HCP)](https://www.msehealthandcarepartnership.co.uk/) which is a partnership of the all the NHS organisations and councils that are responsible for health and wellbeing and the three Healthwatch organisations for mid and south Essex.Areas covered included the boroughs and districts of Basildon, Braintree, Brentwood, Castle Point, City of Chelmsford, Maldon, Rochford, Southend-on-sea and Thurrock
* [The Hospital Saturday Fund](https://hospitalsaturdayfund.org/)
* [The Lanesborough](https://www.oetkercollection.com/hotels/the-lanesborough/)
* [Persimmon Community Fund](https://www.persimmonhomes.com/charity/)
* [Absolutely Offices](https://www.absolutely-offices.co.uk/)

More funds and sponsors will be needed to extend the project to new areas.

**Sources:**

* **Cytosponge-trefoil factor 3 versus usual care to identify Barrett's oesophagus in a primary care setting: a multicentre, pragmatic, randomised controlled trial** - [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31099-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2820%2931099-0/fulltext)
* **Oesophageal cancer survival statistics** - [https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/oesophageal-cancer](https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/oesophageal-cancer/survival#heading-Zero)
* **NICE guidelines oesophago-gastric cancer assessment and management in adults** - <https://www.nice.org.uk/guidance/ng83/evidence/full-guideline-pdf-4723230493>
* **Oesophago-gastric cancers campaign -** <https://www.cancerresearchuk.org/health-professional/awareness-and-prevention/be-clear-on-cancer/oesophago-gastric-cancers-campaign/campaign-overview#BCOC_oesophago-gastric_overview7>

**About Heartburn Cancer UK**

* Heartburn Cancer UK is a specialist cancer charity that raises awareness about the dangers of persistent heartburn, gastro-oesophageal reflux disease (GORD) and Barrett's oesophagus
* It is a recognised and trusted authority in the field of **cancer** of the **oesophagus**, that is helping to make significant inroads in the **prevention**, **detection (especially early diagnosis)** and **treatment** of this disease
* Heartburn Cancer UK wants people to know more about heartburn and other associated issues because these common health concerns can, at times, lead to more serious conditions such as oesophageal cancer
* Heartburn Cancer UK wants people to know more about heartburn and oesophageal cancer because the earlier a problem is highlighted the better the outcome is likely to be
* Heartburn Cancer UK wants people to know that ***if* they regularly have heartburn/acid reflux** (or other similar conditions) **for three weeks or more**, they should go to their GP and tell them about it
* Heartburn Cancer UK raises the dangers of self-medicating with over-the-counter or off-the-shelf medicines when people should actually be talking to their doctor

More information is available on the charity’s website at [www.heartburncanceruk.org](http://www.heartburncanceruk.org)

**About Chelmer Medical Partnership**

* Chelmer Medical Partnership is made up of surgeries in three locations in Chelmsford
* These are Melbourne House Surgery, Humber Road Surgery and Tennyson House Surgery
* The partnership is part of the Chelmsford West Primary Care Network (PCN).

For more information about Chelmer Medical Partnership visit <https://chelmermedicalpartnership.co.uk/>

**About Project DELTA**

* Project DELTA, funded by Innovate UK, aims to improve the diagnosis of oesophageal cancer
* It is a collaboration between the Universities of Cambridge, Oxford, King's College London, the PHG Foundation and Cyted
* Advisory Board support is provided by Action Against Heartburn, Heartburn Cancer UK, the West Yorkshire and Harrogate Cancer Alliance and Newcastle University
* It is developing algorithms to identify individuals most at risk. These people will be offered a Cytosponge™-TFF3 test, which can be delivered in an office setting
* Cyted will develop AI algorithms to assist pathologists with rapid diagnoses. People diagnosed with Barrett’s oesophagus can then be monitored regularly for early signs of cancer

For more information about Project DELTA, go to: [www.deltaproject.org](http://www.deltaproject.org)

**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 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](https://eur02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.cancerresearchuk.org%2F&data=04%7C01%7Cangharad.kolatorbaldwin%40cancer.org.uk%7C4188e9a33bf24576418808d915f43b6d%7C4473892f71e046fc8dec273902b51349%7C1%7C0%7C637564960978676571%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=zNEuHlicWx%2BL4lDlOSN%2B3yUKdAo%2FG1naSv4YUR1Vw8s%3D&reserved=0). Follow us on [Twitter](https://eur02.safelinks.protection.outlook.com/?url=http%3A%2F%2Ftwitter.com%2FCR_UK&data=04%7C01%7Cangharad.kolatorbaldwin%40cancer.org.uk%7C4188e9a33bf24576418808d915f43b6d%7C4473892f71e046fc8dec273902b51349%7C1%7C0%7C637564960978686526%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=crvZ6vwvQSuVemO10H88cK2Y%2BxCUDPSaAQrck0h81TE%3D&reserved=0) and [Facebook](https://eur02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.facebook.com%2Fcancerresearchuk&data=04%7C01%7Cangharad.kolatorbaldwin%40cancer.org.uk%7C4188e9a33bf24576418808d915f43b6d%7C4473892f71e046fc8dec273902b51349%7C1%7C0%7C637564960978686526%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=yoxNA2J7MQRYsL6svQKYU79%2FAOnEaNLhfDz1CMIo034%3D&reserved=0).

**About Medtronic**

Medtronic Plc, which has its headquarters in Dublin, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in approximately 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

For more information, go to: [www.medtronic.com/uk-en/index.html](http://www.medtronic.com/uk-en/index.html)

**About Cyted**

Cyted is enabling the earlier detection of disease, providing products and services that combine proprietary artificial intelligence technology and digital diagnostic infrastructure with next-generation biomarkers.

With significant expertise in pathology, the Company is developing a pipeline of digital and molecular tests for disease detection and risk stratification to streamline diagnostic and clinical workflows. Cyted has the capacity to rapidly implement its sample processing and analysis workflow at scale via Dialogical®, its proprietary pathology reporting platform based on machine learning algorithms.

The Company’s services and products are initially focused on oesophageal cancer, where the combination of an identifiable at-risk population coupled with excellent therapy options offers a unique opportunity to improve patient outcomes through early detection.

Cyted is headquartered in Cambridge, UK. For more information, visit [cyted.ai](https://cyted.ai/)