A trial using the Cytosponge test in GP surgeries for people with heartburn symptoms (BEST3)

This trial was done to see if using a Cytosponge could help diagnose Barrett's oesophagus in people who are on medication for long term heartburn. And to see if it could help detect early cancerous changes. It was supported by Cancer Research UK.

The trial was open for people to join between 2017 and 2019, and the results were published in 2020.

Barrett's oesophagus is a condition where cells on the lining of the oesophagus have changed. It is not cancer, but it does slightly increase the chance of developing cancer of the food pipe known as oesophageal cancer. Many people with Barrett's oesophagus do not go on to develop cancer.

People with Barrett's oesophagus have regular tests to check for any signs of cancer. This helps to make sure they get diagnosed early and can start treatment as soon as possible.

Barrett's oesophagus can be diagnosed by collecting a sample of tissue from the lining of the oesophagus. Doctors often use a small flexible tube with a camera on the end to look at the lining. This is called an endoscopy. They take samples of cells from any areas that don't look normal. But an endoscopy can be uncomfortable and does have some risks.

We already knew from research that the Cytosponge is safe and can be used to help diagnose Barrett's oesophagus.

For the Cytosponge test you swallow a small capsule with a sponge inside, which is attached to a piece of string. The capsule dissolves after a few minutes, and the sponge inside is released. A nurse then gently pulls the string to remove the sponge. On the way out the sponge collects cells from the lining of your oesophagus.

There is more information about having a Cytosponge test in this video.
https://youtu.be/s7X9z6qlNUI

The main aim of this trial was to see how many people were diagnosed with Barrett's oesophagus using a Cytosponge, compared to those having standard care from their GP.

Summary of results

The trial team found that the Cytosponge helped diagnose ten times as many cases of Barrett's oesophagus compared to standard care.

Trial design

The research team identified people who could take part from GP surgeries. This trial was for people who:

- were at least 50 years old
- had been having treatment for acid reflux or heartburn for at least 6 months
- hadn't had an endoscopy within the last 5 years
- had not already been diagnosed with Barrett's oesophagus or oesophageal cancer

The people taking part were put into 1 of 2 groups at random. Half were offered the Cytosponge test, and half had standard GP care.

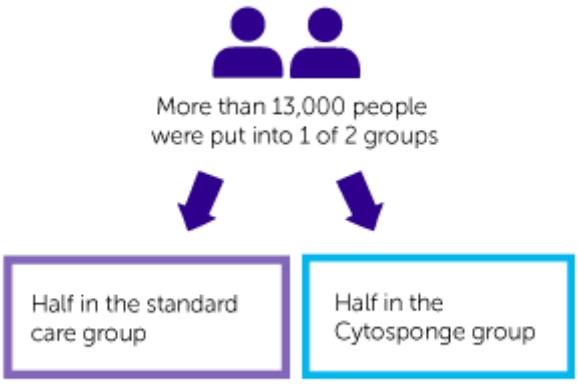
Doctors looked at the cell (tissue) samples that had been taken, to check for signs of abnormal cells. They used an antibody test called TFF3, which has been developed by the research team. Anyone who had a positive Cytosponge result was offered an endoscopy to check whether they had Barrett's oesophagus or oesophageal cancer.

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 earlier stage than those diagnosed in standard care.

Results

The research team identified more than 13,000 people from 109 different GP surgeries across England, who would be able to take part in this trial. They were put into 1 of 2 treatment groups with:

- half in the standard care group
- half in the Cytosponge group



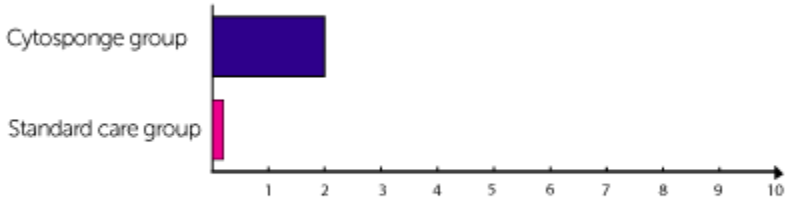
The research team contacted people and asked if they'd be happy to take part in the trial. There were 6,834 people in the Cytosponge group and:

- just under 4 out of 10 people (39%) said they would be happy to take part
- following a telephone call for eligibility and confirmation of their interest in taking part, more than 2 out of 10 people (24%) attended
- just over 6 out of 10 people (61%) either didn't reply or didn't want to take part
- over 9 out of 10 people (95%) who attended for the test were able to swallow the Cytosponge and give a sample of cells

The number of people diagnosed

First, the research team looked at the number of people in each group who were diagnosed with Barrett's oesophagus. It was:

- 140 out of 6,834 people (2%) in the Cytosponge group
- 13 out of 6,388 people (0.2%) in the standard care group



The percentage of people with Barrett's oesophagus

Next, they looked at the number of people who were diagnosed with oesophageal cancer, and what stage the cancer was. There are 4 stages of oesophageal cancer from stage 1 which is early stage, to stage 4 which is more advanced.

Of the 1,750 people in the Cytosponge group who had the test:

- 4 people had stage 1 cancer

Out of 5,084 people in the Cytosponge group who were offered but didn't have the test:

- 1 person had stage 1 cancer
- 2 people had stage 4 cancer

Of the 6,388 people in the standard care group:

- 1 person had stage 2 cancer
- 1 person had stage 3 cancer
- 1 person had stage 4 cancer

Overall, the number of people diagnosed with either Barret's oesophagus or oesophageal cancer was:

- 147 people in the Cytosponge test group
- 16 people in the standard care group

Quality of life
The research team asked the people taking part what they thought about having the test. They asked them to grade how acceptable the test was on a scale of 0 to 10, with 10 being completely acceptable.

1,464 of the 1,654 people who had the test gave it a score. And 1,427 of them (97%) scored it at least 5 out of 10.

Side effects
The Cytosponge test was very safe. People taking part had been told that there was less than a 1 in 100 (less than 1%) chance that they'd need to have an endoscopy if the Cytosponge became detached from the string. This only happened in one person (1 out of 1,654 who swallowed the device), and they had an endoscopy to remove it a few hours later.

Fewer than 1 out of 10 people (4%) had a sore throat for a short time afterwards which in some individuals needed painkillers or affected their eating habits.

Conclusion
The trial team concluded that using the Cytosponge test led to significantly more people being diagnosed with Barrett's oesophagus compared with the standard care group.

In some cases, a positive Cytosponge test also led to a diagnosis of earlier stage oesophageal cancer. The cancers diagnosed from the usual care arm were more advanced.

Future results
The trial team are looking in more detail at how much it would cost if the Cytosponge test was used for more people. They will consider:

- the cost of the test
- the fact that more people will go on to have an endoscopy
- the possibility that people may need less treatment because they are diagnosed sooner
- the effect on people's quality of life

The researchers spoke to patients and health care professionals who took part, to find out more about what they thought of the Cytosponge. They plan to analyse these results and publish the findings.

They also plan to follow what happens to the people who took part in this trial for up to 10 years. They will look at how many people in each group are diagnosed with Barrett's oesophagus or oesophageal cancer, and how many people have died.

Where this information comes from

We have based this summary on information from the research team. The information they sent us has been reviewed by independent specialists and published in a medical journal. The figures we quote above were provided by the trial team who did the research. We have not analysed the data ourselves.

Recruitment

Start 01/04/2017
End 01/04/2019

Chief Investigators

Professor Rebecca Fitzgerald
Professor Peter Sasieni

Supported by

- Cambridge University Hospitals NHS Foundation Trust
- Cancer Research UK
- King's College London
- Medtronic
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