Informed Consent Form for Study:

Evaluating Gastro-oesophageal Reflux after Palliative Stenting for Malignant Distal Oesophageal Obstruction using Anti-Reflux Stents: a Randomised Controlled Trial

University of Cape Town Human Research Ethics Committee Approval Number:
HREC REF: 706/2021
NCT Number not yet availbale

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UNIVERSITY OF CAPE TOWN
GROOTE SCHUUR HOSPITAL

Upper Gastrointestinal Surgery Unit
Surgical Gastroenterology
Department of Surgery
University of Cape Town, Faculty of Health Sciences
Anzio Road, Observatory 7925, Cape Town, South Africa

Place Patient Sticker Here

Evaluating Gastro-oesophageal Reflux after Palliative Stenting for Malignant Distal Oesophageal Obstructions using Anti-Reflux Stents: a Randomised Controlled Trial (HREC REF NO: 706/2021)

Consent Form

I, the above-named patient, hereby give consent to enter as a participant into the above-named research study comparing anti-reflux to conventional stents for oesophageal cancer. I confirm that I have read the full information sheet for this study or have had it read to me in a language I understand. I also confirm I have understood the contents of the information sheet and have had the opportunity to ask any questions I have about the trial and have had these questions answered. I understand the purpose of this study and that my participation is entirely voluntary, that I can withdraw from the trial at any point and that by not consenting or withdrawing from the trial my ongoing medical treatment will not be affected in any way. I acknowledge that my information will be used as part of the research study to see whether anti-reflux stents improve acid reflux, and that the researchers will take every reasonable step to protect my privacy and confidentiality.

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person Taking Consent	Date	Signature

If you have any questions or concerns about this study, please contact Dr Matthias Scriba via email at matthias.scriba@gmail.com or via telephone 021 404 2334/ 021 404 3149 (during office hours). ***If you have any concerns about the ethics or ethical approval of the study please contact the University of Cape Town Human Research Ethics Committee (HREC) via email at hrec-enquiries@uct.ac.za or at 021 650 1236.***

We thank you for agreeing to take part in this research study.

Participant Information Sheet

Introduction

You are invited to take part in a research project. Many patients such as you, who have a cancer at the bottom of their oesophagus or food pipe, struggle to swallow food or even liquids when the cancer starts blocking the food pipe. This is called dysphagia and can be very distressing. An effective way to improve swallowing is to place a stent into the food pipe which opens up the blockage the cancer has caused. A stent is a tube made of a very fine wire mesh covered in plastic. One of the side effects of placing such a stent at the bottom of the food pipe, is that the stent can hang into the stomach and disrupt the natural valve we all have at the end of the food pipe. This valve stops acid and food refluxing up the food pipe. A stent can thus quickly help to improve your ability to swallow but the down-side is that it can cause significant acid reflux, which can be uncomfortable.

This research study will compare using a stent with an anti-reflux valve, which may reduce acid reflux, to the normal stents which do not have an anti-reflux valve. These stents have been shown to be safe and just as good as the normal stents in improving swallowing. However, it is not clear whether they really reduce acid reflux.

Who Can Join This Study?

Patients diagnosed with a cancer in the bottom of their food-pipe (oesophagus) who cannot swallow properly and have been found to need a stent will be approached to join the study.

Do I Have to Take Part in this Study?

No, taking part in this study is completely voluntary, which means you have a free choice whether you want to join or not. Whether you decide to join the study or not will not affect whether or not you receive a stent or any of the usual treatments a patient with a cancer in the food-pipe usually receives. If you do agree to join the trial, you also have the option of withdrawing yourself from the trial at any point.

What Will Happen if I Agree to Join the Study?

The study will be fully explained to you. You will have a stent inserted as per the standard protocol of inserting a stent in the food-pipe. You will receive sedation for the procedure (which means you will have a light sleep while the stent is being inserted). You will not know what type of stent you receive. After the procedure you will be kept in hospital overnight and undergo a safe and painless swallowing test the next morning. If you are well enough to go home, you will then be discharged. You will also be referred to the Palliative Care Team at Groote Schuur Hospital, who are a team of doctors, nurses and other professionals who are experienced and skilled at helping people with life-threatening conditions such as oesophageal cancer. After discharge, the researchers in this study will then phone you at 1, 2, 4 and 8 weeks after the stent insertion and ask you how your swallowing is going, a further 6 questions about any symptoms of acid reflux or heartburn, about whether you are coughing more than usual and

what level of pain you have (using the pain picture scale you see at the end of this sheet). The telephone call will only take a few minutes. If you experience any problems or complications relating to the cancer or the stent, you will be asked to attend your nearest hospital or Groote Schuur Hospital to be assessed by a doctor.

What are the Risks and Disadvantages of Joining this Study?

This study is considered low risk and does not carry any major disadvantages if you agree to join the study. Both types of stents have been shown to improve swallowing to the same degree and are considered equally safe. Although complications and problems can occur when a stent is inserted into the food pipe, this can happen with any stent and being part of this research project does not increase this risk. If you join this study you will be asked to have an extra test which you will not have if you do not join the study. This is the swallowing test the first day after the stent is placed. Although this is an extra test, it involves you eating some soft porridge and standing or sitting in front of a machine. It is not uncomfortable or painful. ***During the test you will be exposed to radiation, which is similar to a standard x-ray, but the level of radiation or radio-activity for this test is extremely small and is very similar to what one is exposed to when living in a large city like Cape Town.***

Are there any Benefits for Me to Join this Study?

If you receive the anti-reflux stent, you may have less acid reflux, but this is not guaranteed. Other than this there will be no direct benefits to you joining, but you will help us to find out if the anti-reflux stents help to reduce acid reflux. This could then help many other people in the future with a similar health problem to yours.

How Long Will the Study Last and What Will Happen When the Study is Over?

The study will last for 2 months (8 weeks) from the day your stent is inserted. Once the study is over you will still be cared for and followed-up by your treating doctors as before and you will still have the same access to health care as before.

Will I Know What Type of Stent I Receive and What the Result of the Study Are?

No, you will not know which type of stent you have received. Once the study is over and all the results of every patient who has been involved in the study are put together, the final outcomes will be published in a medical journal so that others can learn from the study. However, none of the patients involved in this study will know their own personal results.

Will Any of My Blood, Tissue or Other Samples be Stored and Used for Research in the Future?

No, we will not take any blood or tissue samples from you specifically for this study. As part of your work-up for oesophageal cancer you will need a biopsy of the cancer (which is done during your gastroscopy) and some bloods drawn. These are part of the standard work-up all patients need with this type of cancer. No extra blood or other samples will be needed for the purposes of this study.

Who Will See the Information Which Is Collected About Me During the Study?

All your personal and medical information will remain safe. The researchers doing the trial will enter the information onto a safe, password-protected computer and only they will have access to the information. Once the information is put together to look at the results of the study, the information will be anonymised – in other words, your name and hospital number will not be looked at by anyone and no-one will be able to link your medical information to your personal details.

Will I Receive Any Reward for Taking Part in this Study?

No, patients who agree to take part in the trial will not be given any money or other rewards specifically for taking part in this study.

Who do I Speak to (or Contact) if I Have Any Questions About the Study?

If you have any questions or concerns about this study, please contact Dr Matthias Scriba via email at matthias.scriba@gmail.com or via telephone 021 404 2334/ 021 404 3149 (during office hours). ***If you have any concerns about the ethics or ethical approval of the study please contact the University of Cape Town Human Research Ethics Committee (HREC) via email at hrec-enquiries@uct.ac.za or at 021 650 1236.***

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Visual Analog Pain Score (Faces)