TADPOLE Participant Information Leaflet

Targeted Axillary Dissection versus axillary node clearance in patients with POsitive axillary Lymph nodes in Early breast cancer

What are we trying to find out?

We are comparing two types of surgery, one called **TAD** (Targeted Axillary Dissection) and one called **ANC** (Axillary Node Clearance).

We are trying to find out which type of surgery is better at reducing swelling of the arm for patients with early-stage breast cancer, without affecting if the cancer returns or spreads.

What's the difference between the two surgery types?

TAD surgery removes the lymph nodes in the armpit that contain cancer and some surrounding lymph nodes ('sentinel' nodes). These are the first lymph nodes that breast cancer may spread to.

ANC surgery removes most or all armpit lymph nodes. ANC is the standard NHS treatment.

Who do we need help from?

We need over 800 people having surgery for early-stage breast cancer with one or two affected lymph nodes in their armpit.

Which type of surgery will I get if I choose to take part?

The surgery you receive will be **selected at random by a computer.**

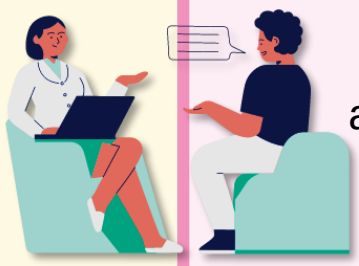
This study has 2:1 randomisation. This means that there will be two people put into the TAD group for each person put into the ANC group.

You will know which surgery you have been chosen to receive at the first study appointment.

How long will I be in the study?

You will be contacted (followed-up) for **at least five years**. You will have the option to agree for your routine medical records being collected for research purposes for longer, but we can only do this if funding is approved.

What will happen next?



A member of your local research team will contact you to **explain the study** and **answer any questions**.

Your local research team will include doctors and research nurses at the hospital where your surgery will take place.

If you choose to take part, your first study appointment will be arranged at your local hospital. We will try and plan this for when you are already coming to hospital for other appointments for your care.

What will I have to do if I choose to take part?

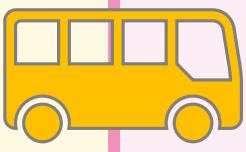
- Sign a **consent form**.
- Complete a questionnaire **before surgery**; at **1, 2 and 5 years** after your last armpit surgery.
- You will be contacted by a member of the research team once a year, **every year after your surgery for at least 5 years**. They will check you are still happy to carry on with the study at every contact.
- **Attend** your local hospital for 2 study appointments. This may be at the same time as other hospital appointments you will have as part of your care. Other study related contacts will not need to be in person.
- We will measure the width of your arm before and at 1 year after surgery to record any swelling of the arm that you may be experiencing.
- You will have a mammogram every year after your surgery for the next 5 years, as part of standard NHS care.

Is there anything else I will be asked to do?

During your surgery tissue is collected for the hospital to test as part of your care.

We will ask if some of this tissue can be sent to another laboratory to create a library of samples. Scientists can then use these samples to **help future patients** with diagnosis and treatment for breast cancer. This tissue will not have your personal information labelled on it.

Will I have to visit the hospital more often?



You will have face-to-face hospital appointments (study visits) to see the local research team. This will happen **once before** your surgery and **1 year after your surgery** and will be arranged alongside other appointments you will have as part of your care.

You will need an **extra NHS appointment** to have an **ultrasound scan** of your armpit if you are put into the **TAD group**.

What are the good things about taking part?

Your help with the study will lead to **better treatments** for early-stage breast cancer **patients in the future**.

If you take part, you will have more contact with your local research team and you can let them know if you have any problems.

What might put me off from taking part?

- You will be asked to spend time completing questionnaires. This will take 15-30 minutes to complete.
- You may need an extra ultrasound scan of your armpit.
- You may not know which type of surgery you will get until slightly later (your first study appointment) than if you received standard NHS care (during your appointment you had today).

Is there anything else I will be asked to do?

You may be contacted by researchers from University of Bristol to take part in an **optional** research **interview** to share your experiences about the study.

This will be over the telephone or in-person and will be **audio-recorded with your consent**.

What information will be collected about me and how will it be used?

CONFIDENTIAL

- We will **collect information** from you and your medical records such as your name, NHS number and about the care you receive for your breast cancer.
- At the end of the study, we will save some of the clinical data in case we need to check it and for future research.
- We may also need to share your mobile number with an external company to be able to send you text reminders about the questionnaires.
- You will be asked if we can share some information about you such as NHS number, date of birth and postcode, with people working on healthcare databases. This is so that they can share information about your medical care **beyond 5 years** with the TADPOLE researchers to see how you are getting on.
- You will be asked if a sample of your tissue collected during surgery can be anonymously sent to a laboratory to improve care for future patients.
- We will keep your data **safe** and **private**.
- We may share your information with other researchers, **but they won't know who you are**.

What will happen if I do not want to carry on with the study?

It's up to you if you want to take part. If you agree to take part and then change your mind, you can leave the study at any time, your medical care won't be affected. You can do this by using the contact details below.

If you feel that you can no longer take part in the study, you can still help by allowing us to collect information from your medical records.

What if I'm not happy and want to make a complaint?

You can contact your local research team or the TADPOLE study team by using the contact details below

TADPOLE Study Team

Bristol Trials Centre (BTC)
University of Bristol
1-5 Whiteladies Road, Bristol, BS8 1NU

0117 455 1524

tadpole-trial@bristol.ac.uk

TADPOLE Pathway

First consultation

Discussion of your treatment options. The consultant will give you a brief introduction to TADPOLE and give you this participant information leaflet .

Research nurse contact

A research nurse contacts you, gives detailed information about TADPOLE, and answers your questions. If you decide to take part, we'll arrange your first study visit.

First study visit

Visit the local hospital, sign a consent form, and provide baseline clinical measurements. Your operation type will then be randomly allocated to you, and you will be told which one you will be having.

Axillary Node Clearance (ANC)

OR

Targeted Axillary Dissection (TAD)

Before surgery (TAD only)

If you are randomised to have the TAD surgery, you will also have an ultrasound scan to mark the lymph nodes to be removed.

Day of surgery at local hospital

Removal of breast cancer and TAD or ANC surgery, and post-surgery care.

1 month after last armpit surgery

Receive a study follow-up phone call to collect health-related information.

1 year after last armpit surgery

Visit the local hospital for your study follow-up to complete questionnaires and clinical measurements.

2, 3, 4 & 5 years after last armpit surgery

Receive study follow-up phone calls to collect health-related information. Questionnaires will be completed in years 2 and 5.

Your surgeon will provide you with more information about your operation, such as what to expect, recovery times and how to prepare for it. If you have any questions about your operation, please contact your surgeon.

Thank you for reading this leaflet and considering taking part in our study.