PRADA-II Trial

Pre-Operative Radiotherapy And DIEP flAp reconstruction – II Trial

Participant Information Sheet

We invite you to take part in our research study

Before you make your decision, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. You can also watch an information video here and look at our website for more information. You may want to talk to friends and relatives about the study before taking part.

Information Video	Study Website
QR code	QR code

You are free to decide whether to take part in this study. If you choose not to take part, be reassured that this will not affect your treatment and your rights as a patient in any way.

You may withdraw from the study at any time if you wish and you do not have to give a reason for withdrawing.

Part 1 – Why is this study being done? (page 3): This section tells you about the purpose of this study and what will happen if you take part.

Part 2 – Frequently Asked Questions (page 13): This section gives you more detailed information about the conduct of the study.

Part 3 – Participant Privacy Notice (page 18): This section explains how we will look after all the information collected about you and use this information properly.

Part 4 – Contact details (page 25): This page includes contact details for the research team and out of hours emergency contacts details.

Part 5 – Glossary (page 26): This section explains some of the terms and words used in this document.

PART 1 - Why is this study being done?

What is the PRADA-II Trial ?

Every year in the United Kingdom (UK), around 15,000 women require mastectomy and lymph node surgery. Of these, one in three undergo breast reconstruction, rebuilding a breast shape, using their own body tissues. Others may choose not to have a reconstruction or may have an implant reconstruction.

Many women will then need radiotherapy to reduce the risk of the cancer returning.

The need for radiotherapy can lead to several problems:

1. Complications after mastectomy with reconstruction can delay radiotherapy
2. Radiotherapy may damage the reconstruction causing firmness, lumpiness and shrinkage, leading to unevenness and discomfort.

As a result, many hospitals do not perform immediate breast reconstruction if radiotherapy is required. These women must wait many months for their reconstructions, and about two out of three women never receiving a breast reconstruction.

Giving radiotherapy to the breast before mastectomy and reconstruction is safe. Evidence shows there is no difference in cancer control whether radiation is given before or after reconstruction.

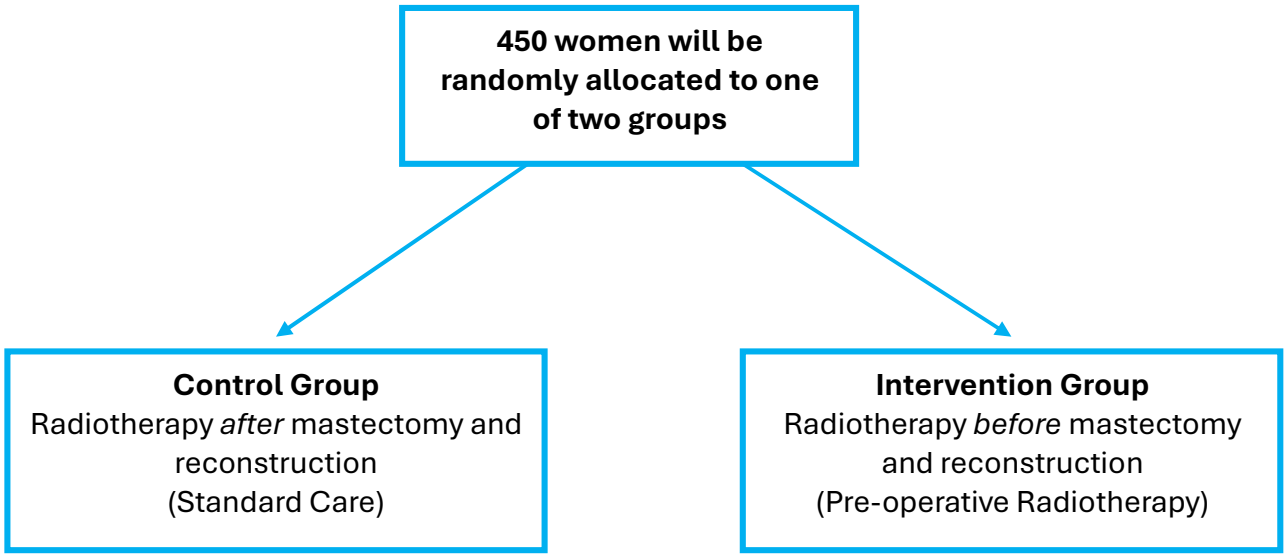
Small studies have shown that giving radiotherapy to the breast first can protect the quality of the breast reconstruction. We believe that giving radiotherapy first will improve patient's satisfaction with the look and feel of the reconstruction. Giving radiotherapy first may also reduce delays and the duration of treatment and allow earlier return to normal activities.

Breast cancer can be emotionally and physically challenging, and with better reconstructions we can improve the way women feel about their body image, confidence, femininity, and sexuality.

We are conducting a large study with 450 patients across 26 NHS hospitals to confirm these early findings. We will compare radiotherapy before mastectomy and reconstruction to radiotherapy after mastectomy and reconstruction.

Why have you been invited?

You are receiving treatment for breast cancer which will involve mastectomy with breast reconstruction and radiotherapy.



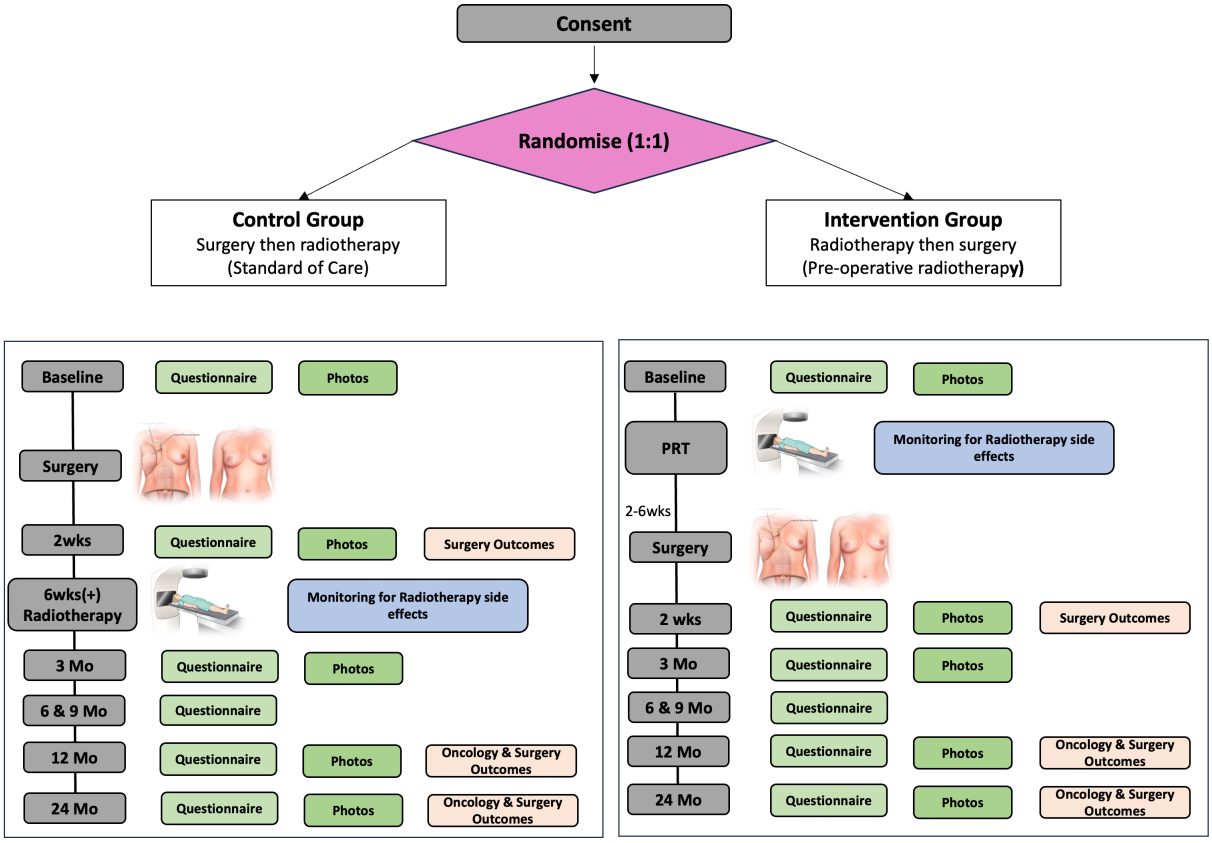
Women will be randomly allocated to one of two groups. This is called randomisation. The decision about whether you will get radiotherapy before or after is made randomly, like flipping a coin. There is an equal chance of getting either option. One group will receive radiotherapy to the breast before mastectomy and reconstruction and the other will receive radiotherapy after mastectomy and reconstruction (standard of care). All women will receive the same number of hospital visits and assessments.

If you agree to take part, you will meet with the oncology, breast surgery and plastic surgery teams, who will ensure that you fulfil the requirements. We will also collect data

about you (e.g. age, ethnicity, etc) and your medical history. These meetings will take place prior to breast surgery and radiotherapy.

What will happen to me if I take part?

If you take part, you will be part of our study for 2 years. There are no additional visits after this time. Below is a flow diagram explaining the visits that are required.



Baseline Visit

You will meet a breast and plastic surgeon and a clinical oncologist. After we have confirmed that you can be included within the study, we will sign a consent form for the study together if you wish to proceed.

The oncology team may recommend an additional PET-CT scan to help plan the radiotherapy treatment area by looking at the lymph nodes in more detail.

You will be asked to complete 2 questionnaires relating to quality of life.

We will also require medical photographs ahead of your surgery. The photographs will be anonymous and will not contain your face. They are stored in a secure way that is compliant with privacy and transfer regulations (HIPPA). Medical photographs are a recommended standard of care for patients undergoing breast reconstruction and make up part of your electronic health record.

Radiotherapy Visits

If you are allocated to have radiotherapy first, it will take place 2-6 weeks before your breast surgery. If you have having chemotherapy as the first treatment, the radiotherapy will happen 3-6 weeks after completion of chemotherapy.

If you are allocated to the receive radiotherapy after surgery, it is given when you are medically fit following your operation, usually around 6-8 weeks after.

In both groups, the radiation dose will be the same. At the end of treatment, we will record any side effects from treatment (skin redness or flakiness for example).

Mastectomy

Your mastectomy and reconstruction will be performed in the same way regardless of which group you are in and will be discussed and planned with you ahead of time.

Post Operative Follow-up

You will receive follow up visits with your team several times after your surgery, at around 2 weeks, at 3, 6 and 9 months and at 1 and 2 years. At these visits we will monitor for outcomes such as wound healing, status of reconstruction and success in long-term cancer control.

You will be asked to complete quality-of-life questionnaires at each visit.

We will ask for your feedback on how you feel about your breast reconstruction through questionnaires at 3 months, 1 year and 2 years after surgery to find out which group is more satisfied with their breasts and quality of life. We will also collect more photos at year 1 and 2 to record the cosmetic outcome.

Optional Surveys and Interviews

We will conduct interviews with some patients with an opportunity to further share your experience in a short survey. If you consent to this aspect, during the interview and survey, you will be asked questions about your experiences. **This is optional and if you don't wish to take part this does not impact you taking part in the PRADA- II study.**

While these are intended to gather valuable insights, there is a small possibility that some questions might be uncomfortable to answer. If at any point you find the interview upsetting, please inform the interviewer immediately. The interview can then be paused or postponed, and if needed, the interviewer can guide you to appropriate support services.

Optional additional biopsies of the tumour bed and blood samples

After routine hospital tests, any left-over tumour tissue samples collected as part of your standard care are stored in the hospital's pathology laboratory. We will seek your permission to retrieve this tissue for current and future research. This request does not involve taking any new samples, simply your permission to access the samples that will be taken as part of your standard care. **This is optional and if you don't wish to donate your standard care samples does not impact you taking part in the PRADA- II study.**

In a small group of patients [treated at Imperial College and Royal Marsden sites] we will invite patients to consent to an additional blood sample before and after

radiotherapy treatment. In patients receiving radiotherapy before surgery, we will invite you to donate an additional tumour biopsy sample before starting radiotherapy.

Sometimes the breast cancer can return in the same breast, or another cancer can develop in your opposite breast. Both situations are unlikely to happen. If, however, you did develop breast cancer again, we would also like to ask your permission to access any scans you may have and collect a small part of tumour tissue taken from any routine biopsies or surgeries performed as part of your standard care in order to help us better understand why cancer occasionally comes back. This request does not involve taking any new samples, simply your permission to access the scans and samples that have already been taken.

These tissue sub-studies will allow us to investigate the effect of radiation on the breast tumour, helping us produce “markers” that predict how well a cancer will respond to radiation and why some cancers return, and this may help further improve breast cancer treatment in the future. **If you decide not to give additional samples you can still be included in the PRADA-II study.**

What are the possible benefits and advantages of taking part?

There are no additional treatment benefits.

Regardless of which group you are in you will receive radiation therapy and mastectomy with an immediate breast reconstruction using your own body tissues.

There may be some benefits to preoperative radiation, but at this stage, these are unproven, and this is the reason we are conducting this study.

Taking part in the study will benefit other patients with a similar condition in the future, particularly regarding breast-related quality of life and accelerating the time between diagnosis and completion of local therapy to the breast.

Preoperative radiation therapy is currently not standard of care, and so the only way to receive this therapy is being a participant in this research study and being randomly assigned to the preoperative radiotherapy group.

We will share our findings with other hospitals within the UK and world-wide **ensuring your privacy** as well as sharing the results with patients both within and outside of the study and members of the public through social media, but **you will not be named**. We will work with breast cancer charities and national associations to inform national guidelines.

What are the possible disadvantages and risks of taking part?

You may experience some side effects from the radiotherapy, but we do not expect these to differ from if you were not taking part in the study. You should report any side effects to your study team at your next visit.

Challenges in deciding radiotherapy needed before surgery

Decision making around whether radiotherapy is needed to the breast alone or additionally lymph node (gland) areas such as under the arm (axilla) or behind the breast bone (internal mammary lymph nodes) is complex. The internal mammary nodes are included when certain factors apply, such as heavy axillary lymph node involvement, that increase the risk of cancer being in one or more of these nodes. The internal mammary chain is not automatically treated as it lies close to heart and lungs and the treatment can be more complex as a result of needing to avoid treating over a set threshold of heart and lung tissue.
Sometimes internal mammary nodes are removed at the time of reconstruction and very occasionally they will contain cancer cells.

If you are allocated to preoperative radiation therapy, and the radiation oncologist judges it unlikely that the internal mammary nodes are involved, there is nevertheless a risk that at mastectomy and immediate breast reconstruction an internal mammary node may be removed and be found to contain cancer. Subsequent radiotherapy to

this nodal chain is challenging as radiotherapy has been given to an adjacent and partially overlapping area, but most patients will go on and receive other drug treatments as part of standard management that we know can eliminate any residual cancer cells.

Additional radiological biopsies

If you have required preoperative chemotherapy, it is important to know whether chemotherapy has worked to kill all the cancer or not, before you start preoperative radiotherapy. This is simply because, if there has not been a complete response to medical therapy, you become eligible for other medical treatment after surgery.

If this applies to you, then to find out whether there is any remaining cancer cells in the original tumour location, your doctors may recommend that you have an additional breast biopsy before radiation therapy is given.

Additional radiation

You are undergoing Radiotherapy as part of your care and if you take part in this study you will also have a sentinel lymph node biopsy, if clinically indicated, and a PET/CT scan, both described below.

1. **Radiation from surgical procedure(s)**

For women who have lymph node involvement at diagnosis, the treatment plan for the lymph nodes in the underarm may depend upon their response to chemotherapy. To help to plan the treatment to the underarm, we may recommend you undergo a small operation on your lymph nodes prior to receiving radiotherapy, (sentinel lymph node biopsy – where a few lymph nodes are removed guided by radio-isotope) rather than as part of your surgery afterwards. This will not be the case for everyone.

2. **Radiation from additional scans**

The PET/CT scan will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. The radiation dose from the PET/CT scan will be very small compared to the dose from the radiotherapy treatment you are receiving. Ionising radiation may cause cancer many years or decades after the exposure. Taking part in this study will not significantly alter the chances of this happening to you.

Technical challenges during microsurgical anastomosis.

Own body tissue reconstruction requires a microsurgical joining of blood vessels (anastomosis). Our prior work has shown that joining blood vessels using microsurgical when radiation therapy has been given first is safe and feasible. Our work did show that in some patients these joins must be redone during the operation if the vessels are found to be more fragile because of radiation (9.1% of the time). Our prior work showed that despite this the reconstruction worked 100% of the time. Put simply, no patients receiving preoperative radiotherapy suffered a failure of the breast reconstruction. It should be noted however, that the national failure rate of breast reconstruction using own body tissues is 2.5%. Our experience is that this failure rate is not worse if you have had radiation therapy to your breast immediately before mastectomy and reconstruction.

Anxiety in answering sensitive questions in surveys or interviews

Some of the questions contained within the questionnaires / breast related quality of life scale involve questions about feelings of femininity and sexual well-being. You may find some of these questions embarrassing or feel anxious when answering them. The research team have extensive experience in delivering these questions and will be looked after during completion of these questionnaires. We will ensure you have a private room to complete the questionnaires. No personal or identifiable information will be obtained, and you will not be identified from your responses. We encourage responses to all questions on surveys to ensure accurate / complete data recording but questions you do not want to answer can be left blank.

If you have consented, in 1:1 interviews you may be asked questions that you feel cause distress. Please inform the researcher and the interview will be paused or postponed. If you declare that you have recently been experiencing depression, suicidal thoughts, intentional self-harm, or express an intention to harm others, the researcher will immediately share this information with your clinical team or appropriate medical service.

Pregnancy

It is possible that if radiotherapy is given to a pregnant woman, it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor.

Will I get paid for participating?

You will not receive any payment for taking part in the research.

Although we will do our very best to coordinate any research-related activities with your standard care appointments, there will be times when you will spend longer at the hospital because you are taking part in this study.

PART 2 - Frequently Asked Questions

What are the alternatives for diagnosis or treatment ?

If you choose not to take part in this study, you will receive the standard treatment for your breast cancer. If you decide not to participate, your other choice is to have radiotherapy after your surgery – this is the control arm in this study.

You do not have to take part in this study, it is completely voluntary. You have the right to decline your participation in the study for any reason and this will not affect the quality of your treatment.

What if new information becomes available ?

Sometimes, during a research project, new information becomes available about the treatment that is being studied. If this happens, a member of the research team will inform you about it and discuss whether you want to continue the study. If you decide to withdraw, your research doctor will arrange for your care to continue. If you decide to continue in study, you will be asked to sign an updated consent form.

Also, on receiving new information, your research doctor might consider it to be in your best interests to withdraw from the study. Your doctor will explain the reasons and arrange for your care to continue. You may also be withdrawn from the study if you are not able to attend the research visits required or follow the research requirements.

What happens when the research stops ?

Once you have completed 2 years of follow-up after your surgery your participation will be complete. You will be followed-up according to the local procedures. You will not be able to have radiotherapy before surgery outside of the PRADA II study. This may change in future depending on the results of this study.

An independent Data and Safety Monitoring Committee and independent Trial Steering Committee are overseeing the study and may stop the study if there are any serious issues.

What if something goes wrong ?

Imperial College London holds insurance policies which apply to this study. If you experiences harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator at your hospital using the contact details on page 22. The normal National Health Service complaints mechanisms are also available to you. If for any reason you are not satisfied with the response, you may contact the college Research Governance and Integrity Team, details can be located in Part 4.

Will my details and information be confidential ?

Yes. All of your personal details will be kept confidential. Any results from the study will not allow you to be identified in any way. Your GP will be informed of your participation in this study.

We will collect your NHS, CHI (Scotland) or H&C (Northern Ireland) number. This, along with your date of birth, may be used to collect information about your cancer status, any additional procedures you have had during the 2 year follow-up, after the study has completed. This will only be used by researchers conducting ethically approved studies. We may also use your date of birth and NHS/CHI/H&C number to collect information from your NHS record if some information is not available when you

take part in the study. Any data collected will not identify you personally and be kept strictly confidential. If you consent, we will also collect your contact details so we can share the results of the study with you.

Your contact details, NHS/CHI/H&C number and date of birth will be stored securely at Imperial College London and handled according to data protection guidelines. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique code number (study ID) instead.

Who is organising and funding this study ?

The study is being organised and run by researchers at the Imperial College London in collaboration with investigators from the Royal Marsden NHS Foundation Trust. The main Investigator of the study is Dr Daniel Leff. It is funded by the National Institute for Health Research and sponsored by Imperial College London. The sponsors of this study will pay your hospital the costs associated for including you in this study but your doctor will not be paid extra for including you in this study.

What if I lose capacity to consent, at some point during the study ?

You would be withdrawn from the study. Data or samples already collected with your initial consent would be retained and used in the study. However, no further data or samples would be collected or any other research procedures carried out.

What will happen to the samples taken during the study?

If you consent to this, we will collect tissue and blood samples as part of this study. All activities (storage, use and disposal) concerning the samples will be carried out in accordance with the Human Tissue Act 2004.

The results of tests performed on stored samples or reports resulting from the analysis of the samples will not be given to you or your doctor and they will not be put in your medical record.

Your sample will be given a unique identification number and stored without your name. Only your research doctor will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If the research team distributes these samples for this, or other ethically approved research, it will be released with the unique identifier only, without any names or medical record numbers. If at any time you would like to have the sample(s) removed from storage, please let us know and it will be transferred or destroyed according to your wishes. It is not always possible to remove samples from storage or to retrieve samples that have already been sent to other research teams.

If there are any surplus samples remaining, we will ask you if they can be stored confidentially for future tests that may become apparent linked with the results of this study or for future research that may not be related to the study of breast cancer. If you do not want any surplus samples to be stored, we will destroy them.

What will happen to the results of the study ?

We will share our findings with other hospitals within the UK and world-wide as well as sharing the results with patients both within and outside of the study and members of the public through social media and the study website. We will do this by sharing results in scientific journals and medical conferences. We will work with breast cancer charities and national associations to inform national guidelines.

Your confidentiality will be always ensured, and you will not be identified in any publication. Only group information and no personal information will be presented. At the end of the study, the results of the study can be made available to you and/or your GP should you wish. This will be in the form of a online results meeting that you will be invited to attend. We will also create an information video of the results and written summaries you can share with family and friends.

Who can I contact for independent research information ?

If you have any questions about being in a research study, you can contact the Trust's Patient Advice Liaison Service (PALS). They will give you advice about who you can talk to for independent advice. The nearest PALS office can be found on the NHS website. You can also ask your GP surgery, hospital or phone NHS111 for details of your nearest PALS.

Who has reviewed the study ?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by [REC NAME to be added post approval] Research Ethics Committee.

Further information

Thank you in advance for considering participation in this study. If you have any questions about this research, the study staff will be more than happy to answer them.

PART 3 - PARTICIPANT PRIVACY NOTICE

How will we use information about you

Imperial College London is the sponsor for this study and will act as the data controller for this study. Being a Data Controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms and primary research data.

The study data will then be fully anonymised and securely archived or destroyed.

The study is expected to finish in December 2031.

For more information / confirmation regarding the end date please contact the study team, see 'What are your choices about how your information is used?' for contact information.

We will need to use information from you and your medical records for this research project. This information will include your name, initials, contact details, NHS/CHI/H&C number and date of birth. People within the college and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that the research is being done properly and the information held (such as contact details) is accurate. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Imperial College London is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Data management plans have been created and reviewed in line with Imperial's Information Governance Policy Framework. This covers the collection, movement, processing and storage of the data.
- Data to be stored in a dedicated secure environment which underpins security measures.
- Data will be stored in ISO 27001 certified environment
- Robust pseudonymisation has been implemented to prevent identification
- Access controls have been implemented to ensure only key personnel can access the data.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

As a university we use personally-identifiable information to conduct research to improve health care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research
- Where special category personal information is involved (most commonly health data, biometric data i.e. finger prints or facial recognition and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes.

International Transfers

There may be a requirement to transfer information to countries outside the UK (for example, to a research partner) for research related purposes to:

- Where necessary to provide access to a data processor / service provider who will utilise your personal data as instructed by us.
- Where data has been collected from outside the UK and requires additional transfer(s) as part of the study activity.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- our partners who analyse your data
- organisations who store your data

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner's Office (ICO) website - www.ico.org.uk
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says

- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website - Personal data breaches: a guide | ICO

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.)
- Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- Research Collaborators / Partners in the study
  - The Royal Marsden NHS Foundation Trust will be helping to analyse the data including the process evaluation study.
  - Institute of Cancer Research will be conducting research on the samples provided.

Potential Use of Study Data and Samples for Future Research

When you agree to take part in a research study, the information and samples collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

Commercialisation

Samples / data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

What are your choices about how your information is used?

You can stop being part of the study at any time, without you giving a reason, but we will keep information about them that we already have. We need to manage your records in specific ways for the research to be reliable.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records / your hospital / your GP]. If you do not want this to happen, tell us and we will stop

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Samples will be stored under an HTA-licensed tissue bank at The Institute of Cancer Research. As sponsor, Imperial College London is the custodian of all the biological samples collected within the PRADA II trial.

Where can you find more about how your information is used ?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/, the leaflet available from www.hra.nhs.uk/patientdataandresearch , the PRADA-II website [insert link] or by asking one of the research team.

Complaint

If you wish to raise a complaint on how we have handled your personal data, please contact please contact the research team first by sending an email to prada2@imperial.ac.uk.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on

020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) - via www.ico.org.uk. The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

Thank you for taking the time to consider participating in this study. If you accept to participate a copy of this information sheet and of the consent form will be given to you and held in your medical record.

PART 4 – Contact Details

Contact for Further Information

If you wish to ask any questions or speak to a member of the research team, please use any of the following contact details:

Name: [name of doctor and/or nurse]

Telephone number: [phone number]

Email: [email]

In an emergency, please contact [Organisation/OOO name] on the following 24-hour contact details:

Name: [name]

Telephone: [phone number]

Email (if applicable): [email]

Imperial College London Head of Research Governance and Integrity details:

Telephone: +44 020 7594 1862

Email: rgit@imperial.ac.uk

PART 5 – Glossary

Term	Explanation
Control group	A group of participants is split in two groups; this half does not get the study treatment or procedure; they will have usual care or usual medicines to provide a comparison for the other treatment or procedures.
Intervention group	A group of participants is split in two groups; this half called the intervention group gets the study treatment or procedure we are testing (the intervention). The other half stays on their regular treatment or procedures.
Lymph Node Involvement	A lymph node, usually in the underarm that contains cancer cells.
Mastectomy	Surgery to remove a breast is called a mastectomy. Sometimes other tissues near the breast, such as lymph nodes, are also removed. This surgery is most often used to treat breast cancer.
Radiotherapy	Radiation therapy (also called radiotherapy) is a cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumours.
Randomisation	Randomisation means that a group of people are split into different groups at random, like flipping a coin; one group is kept on their normal care the others are given a different treatment. For this study, we will split into 2 groups and measure how each group is doing. We will see if one group has experienced better quality of life.

Reconstruction	Rebuilding a breast shape after a mastectomy, using your own body tissues or an implant.
Sentinel Lymph Node Biopsy	A small operation in the under arm to remove, usually 1-4 lymph nodes guided by a radio-isotope, magnetic tracer or dye to test for cancer cells.