Participant Information Sheet (Patient)

Study title: CloseHER2 Home

A study to test the feasibility of a community pharmacy-led pathway for the administration of subcutaneous trastuzumab for HER2 positive breast cancer patients.

Study Researcher: Lisa MacLeod

We would like to invite you to take part in a research study

Before you choose whether or not to take part, we want you to understand why we are doing the study. We also want to tell you what it will involve if you agree to take part. Please take time to read this information carefully. You can ask us any questions you have and talk to other people about it if you want. We will do our best to answer your questions and give you any more information you ask for. You do not have to decide straight away.

Why are we doing this study?

We want to test a new way to deliver cancer treatment using community pharmacies. This study may also be used by Lisa MacLeod as part of a research degree (PhD) by publication with the University of Stirling under the supervision of Dr. Josie Evans.

The number of people with cancer is rising and treatment is getting better, as a result more people are living with cancer. The way we treat people with cancer needs to adapt with this change. Cancer centres are very busy and this sometimes means a long wait for patients to be seen on the day of treatment.

Breast cancer is the most common cancer in the UK. Some people with breast cancer have HER2-positive disease which is usually treated with trastuzumab (Herceptin®). Trastuzumab can be given by a 5-minute injection given under the skin (subcutaneous or SC) or by intravenous infusion (IV or drip) over an hour.

Treatment is given every three weeks for at least 1 year in early stage breast cancer, or until disease progression in metastatic breast cancer.

A previous study asked 467 patients treated with both IV and SC chemotherapy which they preferred. The 5-minute SC injection was preferred by 90% (415 of 467) of patients, mainly because it was quicker and less painful.[1]

There are other reasons people prefer not to come to hospital for trastuzumab. It can remind people about having cancer when they want to move on with their lives. Some patients need to take time off work for appointments. For some people, the hospital is a long distance from home, and difficult to get to because there is no direct bus or it is hard to find a parking space.

Community pharmacists (also known as "Chemists") dispense, sell and offer expert advice about medicines. They can also offer services including administering flu injections and travel vaccines. Pharmacies are based in locations that are easy to get to like high streets, supermarkets and health centres. Community pharmacies are open longer hours than cancer day units. This means they may be a more convenient place for people to get their treatment than hospital.

The information from this study will help us to understand what is important to patients when we plan and design cancer services in the future.

Why have I been contacted?

You have been asked to take part because you are having trastuzumab injections and have finished your chemotherapy. We are looking for 50 patients to try having their injections in a pharmacy instead of coming to hospital. We would like to understand what works well and any improvements that could be made. This will

[1]Pivot X, Gogoro J, Müller V, Curigliano G, Knoop A, et al. Patients' preferences for subcutaneous trastuzumab versus conventional intravenous infusion for the adjuvant treatment of HER2-positive early breast cancer: final analysis of 488 patients in the international, randomized, two-cohort PrefHer study. Ann Oncol 2014;25:1979

help us understand if more patients would prefer to have their injections in a pharmacy in the future.

What does taking part in the study involve?

We would like you to try going to a community pharmacy for your trastuzumab for 4 cycles (12 weeks). The injection will be given by the trained pharmacist in their private consultation room. After you have completed 4 treatments, the rest of your treatment will be given in hospital as before.

We will collect some information from your medical records to help us understand who used the community pharmacy service including your cancer stage, age ethnic background and employment status. We will use your postcode to calculate the distance from your home address to hospital and community pharmacy (the postcode itself will not be documented). This will tell us how much further you have to travel to go to hospital than a pharmacy.

We will record your treatment assessment from nursing notes/care bundle to allow the community pharmacy to monitor how you are tolerating trastuzumab treatment. The pharmacist will also collect the same information your nurse collects about side effects (toxicities) of treatment. This will be added to your hospital record at the end of the study.

The pharmacist will also record how long your appointment lasted so this can be compared to hospital appointments. During the study you remain under the care of the hospital cancer team and will still have access to the helpline.

When you have had 4 cycles of treatment in community pharmacy we would like find out how you felt about it. We will ask you to take part in an interview, either face-to-face or on the phone. We will check with you before starting any interview to make sure you are still happy to take part. If you decide to participate in an interview we will record the discussion, type it up and then erase it from the recording device. We expect interviews to take about half an hour.

If you decide not to take part in the interview at any time, you can opt out at any time by notifying the study team, or asking your pharmacist or nurse to contact us on your behalf.

If you do not want to have any of your injections in community pharmacy, you can still help by letting us collect the following information from your notes. This would be called "study registration". We will collect some information from your medical records to help us understand who used the community pharmacy service including your cancer stage, age ethnic background and employment status. We will use your postcode to calculate the distance from your home address to hospital and community pharmacy (the postcode itself will not be documented). This will tell us how much further you have to travel to go to hospital than a pharmacy.

We will make every effort to accommodate patients who wish to participate, however due to the small number of places available in the study in some cases it may not be possible to identify a pharmacy close enough to every patient who wishes to be involved.

Do I have to take part?

No. It is up to you to choose, taking part in this study is entirely up to you. You can choose to take part or choose not to take part. If you choose to take part you can stop the study at any time. You do not have to give a reason for not taking part or for stopping. If you do not want to take part or want to stop the study the medical care you get and your relationship with the medical or nursing staff looking after you will not be affected.

What will happen to me if I take part?

If you are considering to taking part, your chemotherapy nurse or pharmacist will arrange an appointment for you with a research nurse while you are at hospital for trastuzumab. The research nurse will see you in person or contact you by telephone, if you prefer, to answer any questions you may have about taking part.

When you are happy you have all the information you need, the research nurse will ask you to sign an informed consent form.

Once you have given consent, the researcher will contact you to arrange which of the participating pharmacies you wish to go to for the study. The researcher will contact the community pharmacist and send them prescriptions for four doses of trastuzumab injection. The community pharmacist will then contact you to arrange an appointment to attend the pharmacy for your injection. At your appointment, you will be assessed by the trained community pharmacist (the same way as a nurse in the hospital) to make sure you are fit and well for the injection. If there is any problem, the pharmacist will contact your local cancer team. Otherwise they will administer your injection. They will then arrange the next appointment with you.

The pharmacist will ensure the appointment fits in with you, but should be as close to 3 weeks as possible. The pharmacy will have a trained pharmacist available to give you an injection on the arranged day. In the event that the trained pharmacist has to take urgent leave (e.g. due to ill health) another trained pharmacist will normally be available on the same day to administer your injection as this is part of the requirements for participating pharmacies. In the unlikely event that another pharmacist is not available you will have the choice of taking the next available appointment at the oncology outpatient unit at your hospital.

After you have had four injections in community, the community pharmacist will arrange an appointment for you to get your next injection, and remaining course of treatment, in hospital.

A researcher will contact you to take part in an interview to tell us about your experience. If you agree, they will arrange a suitable time to contact you by telephone or meet with you at your local cancer centre if you prefer. The interview will take about half an hour. During the interview, the researcher will record the conversation on a digital recorder. The recorded conversation will be typed up (transcribed) by the PI or a secretary attached to the CI's clinical team and

anonymised (remove any information which identifies participants). The recording will then be erased.

You will complete your course of injections in hospital and your cancer team will follow up your progress as normal.

If you do not wish to participate in the pharmacy pathway, we would be interested to hear about your reasons why. If you would be happy to discuss this with the research team, the chemotherapy nurse will arrange for you to speak to the research nurse. They will explain what will happen will answer any questions you have. Then when you are happy they will ask you to sign an informed consent form. The research team will then contact you to arrange a suitable time for a half and hour interview to talk about your experiences.

When the study is complete, a summary of the results will be available at Maggie's Dundee and in the oncology department of the cancer centres.

Will taking part in the study affect my usual care?

No. Your usual care will be unaffected. You will continue to have your usual appointments with your oncologist and have access to the oncology helpline.

What are the possible benefits of taking part?

There is no guarantee you will benefit from taking part in this study.
By participating you may:

- Receive treatment closer to home (or workplace if you prefer);
- Have more control over your appointment time;
- Help us understand what people with breast cancer want and need from their health service

What are the possible disadvantages and risks of taking part?

The following risks/burdens were identified by discussion with the Maggie's Dundee breast cancer group who were being or had previously been treated for breast cancer:

Some people might be worried about attending an unconventional (unusual) setting and caregiver for their cancer treatment.

- Only pharmacies with appropriate, private consultation areas and meet all the required service specifications will be able to participate in this study. Pharmacists will be trained to the same level as hospital by a chemotherapy nurse to administer trastuzumab. All pharmacists will be trained to deal with the possible adverse effects of trastuzumab and will have a point of contact in the oncology team for guidance and support if needed.

- Participating pharmacists will have been trained and experienced in administering injections such as flu immunisations. They will be trained to deal with allergic (anaphylactic reactions) and have procedures in place to ensure all staff are aware of action to be taken if required.

- Participants will continue to have access to 24-hour oncology triage service (as per standard care) if they require help out-with working hours.

The lack additional healthcare staff on site e.g. medical staff/doctors, lymphoedema nurse may mean they may have to make an additional appointment compared to when they came to hospital.

In practice, hospital outpatient areas and staff are now full to capacity and would be unlikely to see a patient on the same day without a prior appointment unless it was for urgent review. Any participant attending the pharmacy who requires urgent review will have access to the same arrangements for direct referral as a patient on standard care.

Attending community pharmacy for treatment would result in the loss of hospital staff and patient support network.

On further discussion, patients who had finished treatment, felt that they experienced this loss when they were referred back to primary care (their GP). It is hoped that by attending community pharmacy, this will establish a new and longer-term support system for patients with breast cancer.

You will need to give up some of your time to take part in interviews.

Who is organising and funding this research?

This study is being sponsored by NHS Tayside and the University of Dundee. It is being funded as a Joint Working Project in collaboration with Roche Products Ltd, who make trastuzumab. The study has been organised by Lisa Macleod, Research Pharmacist, Stirling University and Andrew Radley, Consultant in Public Health (Pharmacy), NHS Tayside.

What will happen with the information collected about me?

Identifiable information about you and the information collected about you during the study will be stored by on a password-protected database(s) in the University of Dundee for the purposes of this research study. NHS Tayside staff have access to your data in their daily work, however, only specified members of the research team will have access to information relating to this study. Your identifiable information and coded study information will be stored securely. Specified members of the data management team will also have access to your identifiable information to manage your information and maintain the database.

Your information will be kept securely for five years after the end of the study. After five years it your identifiable information will be removed and the rest of the information will be kept for research purposes. If you would like to be informed about future studies that you might be interested to participate we will ask you to sign a consent to allow us to hold your contact details.

We will ask your permission to tell your GP that you are taking part in this study.

With your permission, the pharmacist or study staff will report to your GP other aspects of your healthcare they become aware of. This could be a previously undiagnosed condition. They will discuss this with you and your consultant first.

We would like to invite you to participate in future studies that may be of interest to you. If you are interested, you can initial the box on the consent form. If you do not wish to be contacted about future studies please leave this box blank. The

research nurse will help you to complete the consent form. You will still be able to participate in this study if you chose not to be contacted in the future.

Information which identifies you will not be published or shared.

Your study information with any information which identifies you removed may be shared with other researchers in the UK.

What if something goes wrong?

If you are concerned about your participation in the study you have the right to discuss your concern with a researcher involved in carrying out the study or a doctor involved in your care.

If you have a complaint about your participation in the study first of all you should talk to a researcher involved in the study. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS [Tayside].

[Complaints and Feedback Team
NHS Tayside, Ninewells Hospital, Dundee, DD1 9SY
Freephone: 0800 027 5507

Email: feedback.tayside@nhs.net]

[Grampian

NHS Grampian Feedback Service
Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE
Telephone: 0345 337 6338

E-mail nhsgrampian.feedback@nhs.net]

[Highland

The Feedback Team, NHS Highland, PO Box 5713, Inverness IV1 9AQ
Telephone: 01463 705997

Email: nhshighland.feedback@nhs.net]

If you think you have come to harm due to taking part in the study there are not any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice but you might have to pay for your legal costs.

Insurance

The University of Dundee and Tayside Health Board are Co-Sponsoring the study. The University of Dundee has a policy of public liability insurance which provides legal liability to cover damages, costs and expenses of claims.

Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which gives legal liability cover of NHS Tayside for this study.

As the study involves University of Dundee staff carrying out clinical research on NHS Tayside patients, these staff hold honorary contracts with Tayside Health Board. This means they will be covered under Tayside's membership of the CNORIS scheme.

Other Scottish Health Boards are participating as study sites and they are also members of CNORIS. This will cover their liability for carrying out the study.

If you apply for health, life, travel or income protection insurance you may be asked questions about your health. These questions might include questions about any medical conditions you have or have had in the past. You might also be asked if you have had any genetic tests or about taking part in this study. We do not expect that taking part in the study will adversely affect your ability to buy insurance. Some insurers may use this information to limit the amount of cover, apply exclusions or increase the cost of insurance. Your insurer may take in to account any medical conditions you have, including any which are diagnosed as part of a research study, when deciding whether to offer insurance to you.

Who has reviewed this study?

The East of Scotland Research Ethics Service REC 2, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Dundee University and NHS Tayside, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. Members of the Maggie's Dundee Breast Cancer Group have reviewed the study and the patient-facing materials.

Contact details for further information

Lisa Macleod, Research Pharmacist
l.m.macleod@stir.ac.uk
Telephone: 07758161328 (Tuesday – Friday)

Andrew Radley, Consultant in Public Health Pharmacy, NHS Tayside
Telephone: 01382 425681 (Monday)

Stefani Unit Research Nurses, Ninewells Hospital, Dundee
Telephone: 01382 496685

Dr Josie Evans, PhD Supervisor, University of Stirling
Telephone: 01786 466352

Thank you for taking time to read this information and for considering taking part in this study. If you would like more information or want to ask questions about the study please complete the attached reply slip or contact the study team using the contact details above.

You can contact us Monday – Friday between 09:00-17:00. Outside of those hours, if you need advice you can contact the helpline number provided by your cancer centre.

Data Protection Privacy Notice

How will personal information be used?

We will only use your personal information to carry out this study.

The University of Dundee and NHS Tayside are the sponsors for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controllers for this study. This means that we are responsible for looking after your information and using it properly. NHS Tayside will keep identifiable information about you for 5 years after the study has finished.

NHS Tayside will use your name, NHS number and contact to contact you about the study. They will use this information to make sure that relevant information about the study is recorded for your care and to check the quality of the study. Staff from University of Dundee and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS Tayside will pass these details to University of Dundee along with the information collected from you and your medical records. The only people in University of Dundee who will have access to information that identifies you will be people who need to contact you to check how the information is collected. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

NHS Tayside will keep identifiable information about you from this study for 5 years after the study has finished.

Personal data

Our study will record details of your treatment with trastuzumab and administration of this medicine.

We will ask you questions about your experiences and views about treatment and use your anonymised comments to inform the study findings

Special Category Personal Data

Data that records details about your health is called special category data. We will collect data about your treatment for breast cancer

Data Controller

Anonymised patient data will be stored on a University of Dundee research database. The NHS Tayside and University of Dundee will act as data controllers.

Lawful processing

The lawful basis for the processing of your personal data is that it is being used for the performance of a task in the public interest or in the exercise of official authority vested in the data controller.

The lawful basis for the processing of your special category personal data is that it is being used for research purposes in accordance with Article 89(1) of the General Data Protection Regulation.

You can find out more about how we will use your information at http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information and https://www.dundee.ac.uk/information-governance/dataprotection/ and at http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm

or by contacting Research Governance, Tayside Medical Science Centre (TASC), 01382 383900 email tascgovernance@dundee.ac.uk

Your rights

Your rights to access, change or move your information are limited, as we need to manage your information in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To protect your rights, we will use the minimum amount of information which is personally identifiable as possible.

If you wish to complain about the use of your information please email dataprotection@dundee.ac.uk or, informationgovernance.tayside@nhs.net or, you may wish to contact the Information Commissioner's Office.