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CloseHER2 Home: a community pharmacy-led pathway for the administration of trastuzumab for HER2-positive breast cancer patients

Submission date 27/01/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 09/06/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/06/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Improvements in treatment and an aging population mean there are more and more people living with cancer. The number of people diagnosed with cancer is expected to be around a million every 10 years. The NHS needs to adapt to treat the rising numbers of patients with cancer.
One way to do this is by using community pharmacists who are highly trained healthcare professionals and are based close to where a patient lives. In the North of Scotland region, patients are likely to live much closer to a pharmacy than their local cancer centre.
Some pharmacists already administer injectable medicines such as vaccines.
We want to see if pharmacists can also administer a breast cancer treatment called trastuzumab.
Trastuzumab is an injection for the treatment of a type of breast cancer called HER2 positive breast cancer. It is given every 3 weeks for a year in early breast cancer, and until it stops being effective if patients have advanced disease.
We will check that it is safe to use community pharmacies to provide this service using the same criteria as NHS site and homecare providers are required to meet.
We will ask patients and staff what they think was good, and what needs to be improved.
Finally, we will work out how long each pathway takes for patients and staff and compare the costs of a community pharmacy service to the hospital pathway.

Who can participate?
Patients from the North Cancer Alliance region of Scotland with a diagnosis of HER2-positive breast cancer who have been prescribed a course of trastuzumab.

What does the study involve?
We will ask patients to have four doses (over 12 weeks) in a community pharmacy close to their home or workplace. The injection will be administered by the pharmacist.

What are the possible benefits and risks of participating?
None

Where is the study run from?
The study is run from NHS Tayside (Dundee)

When is the study starting and how long is it expected to run for?
January 2017 to May 20234

Who is funding the study?
The study is a joint working project funded by NHS Tayside (UK) and Roche (UK)

Who is the main contact?
Dr Andrew Radley, andrew.radley@nhs.scot

Contact information

Type(s)
Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269056

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019ON14, IRAS 269056, CPMS 46865

Study information

Scientific Title
CloseHER2 Home: A feasibility study of a community pharmacy-led pathway for the administration of subcutaneous trastuzumab for HER2-positive breast cancer patients.

Acronym
CloseHER2 Home

Study objectives
A community pharmacy-led pathway for the administration of subcutaneous trastuzumab is a feasible and acceptable alternative to the current service

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/02/2020, East of Scotland Ethics Services REC 2 (Tayside medical Science Centre, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; +44 1382 383871; TAY.eosres@nhs.scot), ref: 19/ES/0143

Study design
Interventional non-randomized feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
HER2-positive breast cancer

Interventions
The intervention under study is a new model of care for the administration of subcutaneous trastuzumab via a community pharmacy-led pathway (CPP). Patients prescribed a course of subcutaneous trastuzumab can elect to have four of their prescribed doses of in a community pharmacy administered by a pharmacist. Eligible patients will be identified by their clinical team when they attend for treatment.

In the conventional pathway, patients prescribed trastuzumab attend for treatment at an oncology outpatient area in a hospital at 3-weekly intervals for the duration of treatment. Pre-treatment assessment and administration of trastuzumab is undertaken by a chemotherapy nurse following a local protocol. Patient who elect for standard care may still consent to interview for the process evaluation.

Patients who consent to the CPP will attend the community pharmacy at 3-weekly intervals to receive their trastuzumab for 4 doses. Pre-treatment assessment and administration of trastuzumab will be undertaken by the pharmacist in their consultation room. They will follow the same protocol as the nurses in the conventional pathway. All participants will remain under the care of the acute oncology service regardless of pathway and will continue to have access to the 24-hour Cancer Treatment Helpline and their local oncology service.

The following data will be collected to compare pathways including:
- Time taken from referral to receiving prescriptions:
- Time taken from ordering to receiving stock
- Duration of appointment
- Distances/travel time to appointment
- Treatment/toxicity assessment (to compare if this was conducted equitably and with sufficient with ease in both settings)
- Population data to assess uptake of the CPP and identify possible barriers

A subset of participants who specifically consent to participation in process evaluation will be invited to participate in semi-structured interviews by telephone or face-to-face. Invitation to re-consent to interview will follow the completion of the fourth cycle of trastuzumab via the CPP and the proceeding cycle in hospital to ensure any matters arising in the transfer or care are collated in the evaluation process.

An economic assessment will compare the relative costs of both pathways; the methodology for this is to be confirmed.

A quality and safety audit will be conducted with an adapted Healthcare Improvement Scotland audit tool (based on the forthcoming update to CEL 30 guidance) to ensure CPP sites meet clinical governance standards.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Trastuzumab

Primary outcome measure
1. Proportion of consenting patients completing 4 cycles of trastuzumab via the Community Pharmacy Pathway (CPP), compared to the eligible cohort of patients (from Chemocare booking system) and also the eligible patients who consented over a period of one year OR maximum recruitment of 50 patients is reached measured at the end of the study using patient records
2. Process evaluation of CPP by qualitative methods including semi-structured interviews with participants receiving the intervention and standard care and staff delivering the intervention and staff delivering standard care measured using interviews at the end of each individual's intervention period

Secondary outcome measures
1. Assess compliance with professional and legal standards set out in the Scottish SACT governance framework audit tool using a patient and staff evaluation via semi-structured interviews at the end of the study
2. Evaluate the practicality of the CPP using patient and staff evaluation via semi-structured interviews at the end of the study
3. Economic assessment of the CPP and the conventional care pathway using NHS Reference costs to model both pathways at the end of the study

Overall study start date
31/01/2017

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. Adult patients, ≥16 years of age
2. Able to provide informed consent
3. Prescribed a course of trastuzumab for the treatment of breast cancer
4. Tolerated at least one dose of subcutaneous trastuzumab administered by a chemotherapy nurse in the acute setting
5. Have a minimum of 4 cycles outstanding in the currently prescribed course

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Unable to provide informed consent
2. History of severe allergic or immunological reactions
3. Less than 4 cycles outstanding in the prescribed course of trastuzumab

Date of first enrolment
01/02/2022

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Study participating centre
Perth Royal Infirmary
Taymount Terrace
Perth
United Kingdom
PH1 1NX

Sponsor information

Organisation
University of Dundee

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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Organisation
NHS Tayside

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Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/index.htm

Funder(s)

Funder type
Industry

Funder Name
Roche

Alternative Name(s)

F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
NHS Tayside

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/10/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available; patients have not specifically consented to the transcripts of their interviews being shared outwith the UK or NHS.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	13/09/2021	28/01/2022	No	Yes
Protocol file	version 2	13/09/2021	28/01/2022	No	No
HRA research summary			28/06/2023	No	No