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Spotting head and neck cancer symptoms in community pharmacies in Dundee and sharing information with GP practices

Submission date 18/04/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/04/2023	**Overall study status** Completed	
Last Edited 01/10/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Head and neck cancers are the fifth most common cancer in Scotland. Over the past 10 years, the number of new cases diagnosed each year has been increasing. There is low awareness of the symptoms of head and neck cancer among members of the public. Too many people are being diagnosed at later stages of disease when the cancer has had a chance to spread. This means that it is more difficult to treat. Earlier diagnosis improves survival.
Community pharmacy in Scotland is now the first port of call for people with minor illness. Symptoms in the early stages of serious disease, such as cancer, can be the same as those of less serious illnesses. Pharmacy teams can help to identify people with symptoms which could be a sign of a more serious illness. They can help to support people in going forward for review at their GP practice (or dentist) sooner.
We want to teach pharmacy staff to identify symptoms of head and neck cancer. We want them to be able to discuss these symptoms with people in a sensitive and reassuring way. Most people with these symptoms will not have cancer but their symptoms do need further review. We want to allow pharmacists to share patient details with GP practices to help patients to take the next step. We want to see if this is a service that members of the public and healthcare professionals will use and support.

Who can participate?
Patients over 18 years of age registered with a GP in Dundee City who go to a participating pharmacy with symptoms of concern

What does the study involve?
Patients who go to a participating pharmacy with symptoms linked to head and neck cancer will get some information to read. A pharmacist will have a discussion in a private consultation area to answer any questions they may have and ask them if they would like to take part in the study. The pharmacist will record some personal details and information about their symptoms. People who agree to take part, and give their permission, will have this information shared with their GP practice and with the study team. The pharmacist will tell them to contact their GP practice on the next working day to make an appointment. They will get a questionnaire to take away to

complete.
The study team will contact patients who have given permission, to offer the chance to take part in an interview about the process.
The team will use patient details to get follow-up information from GP practices and from the hospital, where this applies. The team will keep information secure at all times.
GPs, or other practice clinicians, involved in reviewing patients, will get the chance to provide feedback by completing a questionnaire and doing an interview. This opportunity will also be given to participating pharmacists.

What are the possible benefits and risks of participating?
Most people with symptoms will not have cancer, but their symptoms do need further review. People may be upset by hearing that their symptoms may be a sign of serious illness. All concerns will be handled in a sensitive way by the pharmacist. People will be given information on support services available in their local area. Taking part will mean a longer consultation in the pharmacy but will allow the pharmacist to share details with the GP practice. This means the GP practice will have details ahead of the patient's appointment. Taking part will also give people the opportunity to provide feedback on the process by completing a survey or doing an interview. This will give information about whether this type of service is possible to provide from pharmacies.
Patients who do not wish to take part can follow the advice given to them by pharmacy staff. They can contact their GP (or dentist) for a review of their symptoms without having their information shared in advance.

Where is the study run from?
The study is being sponsored by NHS Tayside. It will be run in some community pharmacies in Dundee (UK).

When is the study starting and how long is it expected to run for?
April 2022 to February 2024

Who is funding the study?
1. Scottish Government
2. Merck, Sharp and Dohme (MSD)

Who is the main contact?
Dr Andrew Radley, a.radley@dundee.ac.uk

Contact information

Type(s)
Principal investigator

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
316795

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 316795, CPMS 56272

Study information

Scientific Title
Introduction of a Head and Neck Cancer General Practitioner communication pathway in Community Pharmacies in NHS Tayside (CP HNC GP Communication Pathway)

Acronym
CP HNC GP Communication Pathway

Study objectives
To assess whether a community pharmacy head and neck cancer pathway is acceptable to service users and staff.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/02/2023, London - Camberwell St Giles Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; + 44(0)207 104 8156; camberwellstgiles.rec@hra.nhs.uk), ref: 22/LO/0925

Study design
Single-centre interventional non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Identification of possible head and neck cancer symptoms in community pharmacy

Interventions
Any eligible person presenting to a participating community pharmacy with symptoms of concern, linked to possible head and neck cancer, will be offered the opportunity to take part in the study.
Following an initial consultation with pharmacy counter staff and the pharmacist they will be given a patient information leaflet and allowed time to read it.
If they are happy to proceed with a consultation, the pharmacist will answer any questions they may have about the study and go through the informed consent form with them. This will take place in a private consultation area in the pharmacy.
The pharmacist will then take the patient's details and complete the symptom assessment form by documenting details of their symptoms and some lifestyle information, along with patient details (name, address, CHI, phone number).
The pharmacist will advise the patient to contact their GP practice on the next working day to request an appointment. They will provide them with an additional information leaflet, outlining next steps and providing information on available information resources and support. The pharmacist will then share details of the consultation with the patient's GP and the study team. GP practices, and secondary care services where applicable, will be contacted by the study team for follow-up information. Patients who have consented will be contacted by the project team for a follow-up questionnaire/interview. Participating GPs/clinicians and community pharmacists will also be offered the opportunity to complete a questionnaire/interview.

Intervention Type
Other

Primary outcome(s)
1. Acceptability of the pathway is measured by:
1.1. Patient/public uptake at baseline
1.2. Patient/public feedback via questionnaire at 0-4 weeks and/or interview at 4 weeks
1.3. Pharmacy team feedback at week 24 (end of the recruitment period)
1.4. GP/practice staff feedback via questionnaire at week 4 and/or interview at week 24

Key secondary outcome(s))

1. Can a community pharmacy pathway identify people suspected of having head and neck cancer? Measured by number of completed community pharmacy head and neck cancer assessment tools at baseline.
2. To assess whether community pharmacists can accurately and reproducibly utilise the symptom assessment tool to enable confidence in their use by referral recipients. Measured by GP/practice staff feedback via questionnaire at week 4 and/or interview at week 24.
3. Do people advised by community pharmacy teams to seek further review, attend for further assessment of their symptoms? Measured by obtaining information on participant follow up with general practices at week 4.
4. Are people identified by this pathway referred onwards by primary care for further investigations? Measured via participant follow-up via national datasets using CHI number at week 24.

Completion date
28/02/2024

Eligibility

Key inclusion criteria
1. Any adult (age 18 years+), registered with a GP in Dundee City, who presents to one of the participating pharmacies with relevant symptoms as outlined in the protocol
2. Participating community pharmacists
3. GPs/clinicians who review patient participant(s)

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. People without symptoms meeting study criteria
2. People not registered with a GP in Dundee City
2. Non-consenting individuals
3. Any person under the age of 18 years
4. Any person unable to participate in a consultation conducted in the English language

Date of first enrolment
10/05/2023

Date of final enrolment
15/12/2023

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Tayside
Kings Croos
Clepington Road
Dundee
United Kingdom
DD3 8EA

Sponsor information

Organisation
NHS Tayside

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp and Dohme

Alternative Name(s)
MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Scottish Government

Alternative Name(s)
The Scottish Government, Scottish Executive, Riaghaltas na h-Alba

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes