ISRCTN13709798 https://doi.org/10.1186/ISRCTN13709798

Feasibility study followed by a randomised controlled trial to test a new patient-led follow-up method for low-risk head and neck cancer patients

Submission date
15/10/2021

Recruitment status
No longer recruiting

Registration date
03/11/2021

Overall study status
Ongoing

Last Edited
21/10/2026

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to test the new patient-led follow-up method for low-risk head and neck cancer patients in a small number of patients before testing in a larger clinical trial. Currently, people who finish treatment for head and neck cancer attend a clinic review every 2 to 6 months for 5 years to check if the cancer has come back (called recurrence). If caught early, there is a better chance of successful treatment. However, most patients feel they are seen too frequently, which can increase their worry about cancer recurrence. It is also inefficient because few cancers are found this way. Recurrent cancers are much more likely to be found when patients ask to be seen because their symptoms have changed. Studies also show that a type of scan, called PET-CT, done 1 year after treatment can identify patients who are unlikely to get recurrence and could therefore be followed up less frequently.

Who can participate?
Patients aged 18 years and over with head and neck cancer 1 year after completing curative-intent treatment (surgery, radiation or combination treatments), with no clinical symptoms or signs of loco-regional or distant metastasis (i.e. that the cancer has spread)

What does the study involve?
Patients have a PET-CT scan 1 year after finishing treatment. If no cancer is detected, they will be educated by a nurse, clinical nurse specialist, speech and language therapist or dietitian about what symptoms of recurrent cancer to look out for. The information will also be given as a mobile app/website or paper booklet. They will then be given an ‘open urgent appointment’ guaranteeing review by their clinical team within 2 weeks if they develop worrying symptoms. They will not have to attend regular clinic visits.

What are the possible benefits and risks of participating?
A possible benefit of taking part is to contribute to improving follow-up care of head and neck cancer patients. The PET-CT scan can, if positive, detect recurrent cancer earlier or, if negative,

will provide some reassurance. It also gives participants access to the latest technology for checking the recurrence of cancer (PET-CT scan), which is not currently available as a routine clinical practice. Research has shown that if cancer is detected earlier there are better chances of successful treatment. Participants will have an open urgent appointment so that they are able to see their clinical team within 2 weeks of reporting/contacting if any new or worrying symptoms appear. Participants may find patient-led follow-up more flexible and tailored to their needs as less frequent clinical visits may save the time and money involved in travelling to the hospital.
Participants will have a positron emission tomography-computed tomography (PET-CT) scan as part of their participation in the study. This will be extra to any other scan that they would have if you did not take part in the study. This procedure uses ionising radiation to form images of the body and provide doctors with other clinical information. Ionising radiation may cause cancer many years or decades after exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in the feasibility study will increase the chances of this happening by about 0.07%. It is possible that discussing issues surrounding cancer and follow-up care may be challenging and may cause distress. The interview will be conducted by an experienced and sensitive researcher and participants don't have to answer anything they are not comfortable discussing. However, if they do have any distress after taking part in the interview, they can contact their Clinical Nurse Specialist.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
August 2019 to September 2027

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mrs Yolande Jefferson-Hulme, PETNECK2 trials office, petneck2@trials.bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
298368

Central Portfolio Management System (CPMS)
50360

Protocol serial number
RG_21-035

Study information

Scientific Title
A PET-CT guided, symptom-based, patient-initiated surveillance versus clinical follow-up in head neck cancer (PETNECK 2)- Feasibility Study followed by randomised controlled trial (RCT)

Acronym
PETNECK2

Study objectives
Current study hypothesis as of 19/01/2024:
The feasibility study will test the feasibility of the intervention developed in an earlier part of the programme (PET-CT guided, patient-initiated follow-up), specifically to assess if patients and clinicians accept the intervention and if the proposed intervention can be tested in a clinical trial and amended if necessary.

In the RCT, we propose patients in the intervention arm of the trial would receive an additional PET-CT scan at around 1 year after completion of curative intent treatment. This additional PET-CT scan at entry to the trial will identify some patients with asymptomatic recurrence, but importantly will also identify those at very low risk of future recurrence. These low-risk patients instead of having regular scheduled follow-up appointments would then be in control of when they return for follow-up (patient-initiated follow-up) based on their symptoms (symptom-based). Low-risk patients will receive access to an App, a face-to-face information and support education session which would aim to educate and empower them by giving information on how to monitor their symptoms, understand which "red-flag" symptoms could indicate recurrence, and how to arrange an urgent follow-up appointment (within two weeks) if they develop such symptoms.

The feasibility study closed on 31/08/2022 after recruiting 32 patients. The RCT opened to recruitment on 05/01/2023

Previous study hypothesis:
To test the feasibility of the intervention developed in an earlier part of the programme (PET-CT guided, patient-initiated follow-up), specifically to assess if patients and clinicians accept the intervention and if the proposed intervention can be tested in a clinical trial and amended if necessary.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 14/09/2021, Yorkshire & The Humber- South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 1048091; southyorks.rec@hra.nhs.uk), ref: 21/YH/0175

2. Approved 17/01/2023, Yorkshire & The Humber- South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 1048091; southyorks.rec@hra.nhs.uk), ref: 21/YH/0175

Primary study design
Interventional

Study design
Single-arm multicentre prospective feasibility study followed with an unblinded multicentre non-inferiority Phase III randomized controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Head and neck cancer

Interventions
Patients have a PET-CT scan around 1 year after finishing treatment. If no cancer is detected, they will be educated by a nurse, clinical nurse specialist, speech and language therapist or dietitian about what symptoms of recurrent cancer to look out for. The information will also be given as a mobile app/website and/or paper booklet. They will then be given an ‘open urgent appointment’ guaranteeing review by their clinical team within 2 weeks if they develop worrying symptoms. They will not have to attend regular clinic visits.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measure as of 24/01/2024:
Feasibility:
1. Patient recruitment and consent rates determined as a proportion of eligible patients measured using screening logs and informed consent forms completed at the 6-month timepoint
2. Patient dropout rates measured using withdrawal forms received at the 6-month time point
3. Patient-reported outcome completion rates measured using questionnaires completed at the 6-month timepoint
RCT: Overall survival time

Previous primary outcome measure as of 19/01/2024 to 24/01/2024:
Feasibility: There was no primary outcome measure
RCT: Overall survival time

Previous primary outcome measures:
1. Patient recruitment and consent rates determined as a proportion of eligible patients measured using screening logs and informed consent forms completed at the 6-month timepoint

2. Patient dropout rates measured using withdrawal forms received at the 6-month time point
3. Patient-reported outcome completion rates measured using questionnaires completed at the 6-month timepoint
4. Duration of centre set-up measured using the average length of time for each site to set-up at the 6-month timepoint
5. Qualitative data on patient and clinician acceptance of the intervention and nurse/allied health professionals views towards the training and delivery of the PETNECK2 Education Session, measured using app/booklet use at the 6-month timepoint

Key secondary outcome(s)

Current secondary outcome measure as of 24/01/2024:
Feasibility;
1. Duration of centre set-up measured using the average length of time for each site to set-up at the 6-month timepoint
2. Qualitative data on patient and clinician acceptance of the intervention and nurse/allied health professionals' views towards the training and delivery of the PETNECK2 education session, measured using app/booklet use at the 6-month timepoint
RCT:
1. Patient experience as assessed by the CQC friends and family question ‘Overall, up to this point in time how was your experience of cancer follow-up in the PETNECK2 trial?’ at 6, 12 and 24 months follow up
2. Fear of Cancer Recurrence as assessed by the 9-item FCR Inventory Short form questionnaire at baseline, 12 and 24 months.
3. Quality of life as assessed by the EQ-5D-5L questionnaire, at baseline, 6, 12 and 24 months follow up.
4. Quality of life as assessed by the EORTC General QLQ-C30 and head and neck specific H&N43 questionnaires at baseline, 12 and 24 months.

Previous secondary outcome measure as of 19/01/2024 to 24/01/2024:
Feasibility;
1. Patient recruitment and consent rates determined as a proportion of eligible patients
2. Patient dropout rates
3. Patient-reported outcomes completion rates (whether patients can complete and return them adequately)
4. Duration of centre set-up measured using the average length of time for each site to set-up at the 6-month timepoint
5. Qualitative data on patient and clinician acceptance of the intervention and nurse/allied health professionals' views towards the training and delivery of the PETNECK2 education session

RCT:
1. Cost-effectiveness measured using incremental cost per quality-adjusted life year gained (using EQ-5D-5L) and resource use data collection, including number and reasons for healthcare visits (including nurses and GPs)
2. Recurrence and distant metastasis:
2.1. Disease-free survival time
2.2. Time from treatment to first detection of recurrence
2.3. TNM stage at detection of recurrence; subsequent treatment on recurrence
2.4. Patient experience, fear of recurrence and patient self-efficacy measured quantitatively using questionnaires and qualitatively by patient interviews
2.5. Quality of life measured using the EQ-5D-5L, EORTC General QLQ-C30 and head and neck-

specific H&N43 questionnaires
2.6. Duration to receiving urgent appointment (intervention arm only)
2.7. Number and timings and reasons for appointments requested (intervention arm only)

Previous secondary outcome measures:
There are no secondary outcome measures

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 19/01/2024:
Feasibility :
1. Histological or cytological confirmation of oral, laryngeal, hypopharyngeal or oropharyngeal squamous cell carcinoma
2. Patients at least 6 months post completion of curative-intent treatment by any modality (surgery, radiation or combination treatments), with no clinical symptoms or signs of loco-regional or distant metastasis
3. Patients must be aged 18 years or older
4. Provision of informed consent prior to any study-specific procedures

RCT:
Inclusion Criteria – Registration Stage
For inclusion in the registration stage of the RCT, patients should fulfil the following criteria:
1. Histological or cytological confirmation of oral, laryngeal, nasopharyngeal, hypopharyngeal or oropharyngeal squamous cell carcinoma
2. Patient at 6 – 14 months post curative intent treatment by any modality (surgery, radiation or combination treatments), with no clinical symptoms or signs of loco-regional or distant metastasis
3. Provision of informed consent prior to any study-specific procedures
4. The patient must be aged 18 years or over
5. Willingness to comply with the protocol for the duration of the study

Inclusion Criteria – Randomisation Stage
For inclusion in the RCT, patients should fulfil the following criteria:
1. Patient with no clinical symptoms or signs of loco-regional or distant metastasis or no evidence of recurrent cancer
2. Patient at 11-14 months post curative intent treatment by any modality (surgery, radiation or combination treatments)
3. Patient willing to comply with the protocol for the duration of the study

Previous participant inclusion criteria as of 13/10/2023 to 19/01/2024:
1. Histological or cytological confirmation of oral, laryngeal, hypopharyngeal or oropharyngeal squamous cell carcinoma
2. Patients at least 6 months post completion of curative-intent treatment by any modality (surgery, radiation or combination treatments), with no clinical symptoms or signs of loco-regional or distant metastasis
3. Patients must be aged 18 years or older
4. Provision of informed consent prior to any study-specific procedures

Previous participant inclusion criteria:
1. Histological or cytological confirmation of oral, laryngeal, hypopharyngeal or oropharyngeal squamous cell carcinoma
2. Patients at one year after curative-intent treatment by any modality (surgery, radiation or combination treatments), with no clinical symptoms or signs of loco-regional or distant metastasis
3. Patients must be aged 18 years or older
4. Provision of informed consent prior to any study-specific procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current participant exclusion criteria as of 19/01/2024:
Feasibility :
1. Patients with non-squamous cell carcinoma tumours, or those from sites other than those stated in the inclusion criteria
2. Patients who are pregnant
3. Patients with clinical symptoms or signs of loco-regional or distant metastasis
4. Any patient already enrolled in a clinical trial where scheduled follow-up is a requirement of that trial protocol
5. Significant concern by patient or clinician regarding the ability of patient to undertake patient-initiated follow-up (must record in the Screening/Enrolment Log)
RCT:
Exclusion Criteria – Registration Stage
Patients should not be registered in the RCT if any of the following apply:
1. Patient with non-squamous cell carcinoma tumours, or those from sites other than those stated above
2. Patient who is pregnant
3. Patient with clinical symptoms or signs or radiological evidence of loco-regional or distant metastasis
4. Patient with confirmed unknown primary cancer

5. Patient already enrolled in a head and neck clinical trial where scheduled follow up is part of the trial protocol
6. Significant concern by patient or clinician regarding the ability of patient to undertake patient initiated follow up (must record in the Screening/Enrolment Log)

Exclusion Criteria – Randomisation Stage
Patients should not be randomised in the RCT if any of the following apply:
1. Patient who has relapsed or presented with cancer recurrence since registration
2. Patient who is pregnant
3. Any patient enrolled in a head and neck clinical trial where scheduled follow up is part of the trial protocol

4. Significant concern by patient or clinician regarding the ability of patient to undertake patient initiated follow up

Previous participant exclusion criteria as of 13/10/2023:
1. Patients with non-squamous cell carcinoma tumours, or those from sites other than those stated in the inclusion criteria
2. Patients who are pregnant
3. Patients with clinical symptoms or signs of loco-regional or distant metastasis
4. Any patient already enrolled in a clinical trial where scheduled follow-up is a requirement of that trial protocol
5. Significant concern by patient or clinician regarding the ability of patient to undertake patient-initiated follow-up (must record in the Screening/Enrolment Log)

Previous participant exclusion criteria:
1. Patients with non-squamous cell carcinoma tumours, or those from sites other than those stated above
2. Patients who are pregnant
3. Patients with clinical symptoms or signs or radiological evidence of loco-regional or distant metastasis
4. Any patient already enrolled in a clinical trial where scheduled follow-up is part of that trial protocol

Date of first enrolment
14/02/2022

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Queen Elizabeth Hospital
Mindehlsohn Way
Birmingham
England
B15 2TT

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data will not be made available while the study is ongoing and data will be stored at the CRCTU, within the Robert Aitken Building, University of Birmingham. The datasets generated and

/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/02/2026	02/03/2026	Yes	No
Protocol article		10/07/2024	11/07/2024	Yes	No
HRA research summary			28/06/2023	No	No
Study website		11/11/2025	11/11/2025	No	Yes