ISRCTN18055040 https://doi.org/10.1186/ISRCTN18055040

Yorkshire kidney screening trial

Submission date
11/03/2021

Recruitment status
No longer recruiting

Registration date
14/04/2021

Overall study status
Completed

Last Edited
25/09/2024

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Kidney cancer is the 8th most common cancer in Yorkshire. It has a poor survival rate, with only 6 out of 10 patients diagnosed with kidney cancer still alive after 5 years. This is partly because many people with kidney cancer don't have any symptoms. In some of these people, kidney cancer is only found by chance during investigations for other reasons. In others, it is often not diagnosed until the disease has passed the point at which we can easily cure it.

Screening for kidney cancer has the potential to pick up these cancers earlier and increase the number of people who can be cured. The Yorkshire Lung Screening Trial offers people, aged 55-80 with a history of smoking, a CT scan as part of a lung health check. This group of people is also at increased risk of developing kidney cancer. Our new study, the Yorkshire Kidney Screening Trial, will piggyback on this trial to offer an extra CT scan for kidney cancer. The extra scan will take 10 seconds. By the end of the study we will understand whether it is workable to roll this out more widely and whether people take up this extra scan.

Who can participate?
All participants attending the second scanning round (T2) of the Yorkshire Lung Screening Trial.

What does the study involve?
Participants will be invited by telephone to attend the YLST T2 scan. When they arrive at the YLST van they will be shown the YLST introduction video followed by the YKST video. The YLST consultation will then take place in a separate room. After the YLST components are completed, participants will be asked if they would like to take part in YKST. Participants wishing to take part, will be given the Participant Information Sheet and informed written consent will be sought. They will then be asked a small number of RCC specific questions (history of diabetes, high blood pressure, medication for high blood pressure, family history of kidney or pancreatic cancer, alcohol intake) before having the CT scan. For consenting participants, an abdominal CT scan will be conducted after the lung CT. Participants will not have to change position, and the abdominal scan will take an extra 10-15 seconds.

All participants approached to participate in YKST (both those who wish to take part as well as those who decline) will be asked if they consent to be contacted by a University of Cambridge researcher, to discuss taking part in a qualitative research interview about reasons for agreeing, or declining, to participate in YKST. Participants who do agree to take part in the interview study

will be sent a separate Patient Information Sheet and consent form. A time and date convenient for the participant will then be arranged for a telephone or remote video interview.

What are the possible benefits and risks of participating?
For participants being offered YKST screening, the main benefit will be the potential to identify kidney cancers at an early stage, which can often be treated and cured. The CT scan may also pick up findings in the kidney which are not cancer but which require further investigations. Although the extra CT scan is being done to look at the kidneys, it will also include the upper abdomen, and may pick up problems in other organs, including the liver, pancreas and aorta. If such problems are detected, participants will be referred to the appropriate specialists.

CT scanners use radiation, which can itself cause problems (very rarely actually causing cancer), but by using very modern CT scanners we can reduce the amount of radiation needed. The extra CT scan of the kidneys will slightly increase the amount of radiation participants are exposed to. This extra dose is the same amount of radiation that participants would come into contact with in daily life, over a 12 month period. The likelihood of this scan detecting an early cancer is far greater than the likelihood of the scan causing harm.

Occasionally, people may have unnecessary investigations because findings later turn out to be benign (not cancer) or a harmless kidney cancer (that would not cause problems even if left alone).

Participants may feel anxious about what the scan may find, and about any further investigations they may need as a result of these findings. The doctors and nurses involved in the trial will always be available to discuss any concerns participants may have.

Where is the study run from?
The University of Cambridge, in close collaboration with the YLST team who are based in Leeds Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2021 to April 2023

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Professor Grant Stewart, gds35@cam.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Grant Stewart

ORCID ID
https://orcid.org/0000-0003-3188-9140

Contact details

University of Cambridge
Department of Surgery
Cambridge
United Kingdom
CB2 0QQ
-
gds35@cam.ac.uk

Type(s)
Public

Contact name
Ms Jessica Kitt

ORCID ID
https://orcid.org/0000-0003-0134-5564

Contact details
University of Cambridge
Department of Surgery
Cambridge
United Kingdom
CB2 0QQ
-
jk896@cam.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
290336

ClinicalTrials.gov (NCT)
NCT05005195

Protocol serial number
IRAS 290336

Study information

Scientific Title
Yorkshire Kidney Screening Trial (YKST): a feasibility study of adding non-contrast abdominal CT scan to chest CT scan undertaken in the YLST randomised controlled trial of community-based CT screening for lung cancer in an at risk population to screen for RCC and other abdominal malignancies.

Acronym
YKST

Study objectives
This is a feasibility study aiming to pilot procedures required for a subsequent full-scale RCT of RCC screening by non-contrast CT scanning within lung cancer screening; investigating the take up of the abdominal CT scan to screen for RCC, acceptability of the intervention to patients and health care professionals, as well as logistics around delivering the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/02/2021, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8206; preston.rec@hra.nhs.uk), ref: 21/NW/0021

Study design
Interventional non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Screening for renal cell carcinoma (RCC) in participants of the Yorkshire Lung Screening Trial

Interventions
Participants taking part in the study will be offered a non-abdominal CT scan at their T2 (2 years after baseline) YLST study visit.

Participants taking part in the Yorkshire Lung Screening Trial (YLST) are invited to the T2 YLST study visit, either by telephone or letter, and a clinic appointment is arranged. When participants arrive on the mobile van for the YLST T2 visit, they are given an iPad to watch the YLST PIS video, after which they are informed of YKST and are invited to continue watching the YKST study PIS video. Participants then complete the YLST T2 consultation. If they would like to take part in YKST, participants are asked to sign the YKST consent form and complete a short YKST baseline questionnaire. Participants then leave the consultation room to have their lung non contrast CT scan, followed directly by the non-contrast abdominal CT scan. Participants then leave the mobile van. This all happens over 1 day. Results are feedback to participants within 2-4 weeks, and any findings that require follow up are done so by the relevant clinical team, as per Leeds Teaching Hospitals Trust standard clinical practice.

Participants who consent to being contacted for an interview will be contacted (by email/phone /letter) by a YKST team member from the University of Cambridge and asked if they would like take part in an interview. If so, they will be sent the YKST interview PIS and asked for consent. An interview (either by video call or telephone) will be arranged at a time convenient to the participant and will last approximately 30 – 45 minutes.

Relevant clinical outcomes will be followed up after 10 years (with the patients' consent) by reviewing their patient notes.

Intervention Type
Other

Primary outcome(s)
1.The proportion of individuals attending the T2 round of YLST who take up the offer of an abdominal CT scan measured using patient records, reports and study visit logs. Calculated at a single time point
2. The acceptability to participants of combined lung and RCC screening by non-contrast CT scanning measured using interviews within 3 months of the invitation to the study
3. The acceptability to healthcare professionals involved in the screening of combining RCC screening by non-contrast CT scanning with lung cancer screening measured using interviews within 6 months of study start
4, The additional time required for the combined screening approach, including the time to provide information, consent participants, and perform the lengthier CT scan, the time needed by radiologists for reporting the CT scans, and the additional time to review abdominal CT findings measured using timing sheets at a single time point

Key secondary outcome(s))
Current secondary outcome measures as of 04/02/2022:
1. The proportion of participants found to have a renal mass or RCC measured using CT at a single time point
2. The stage distribution of RCC identified through non-contrast CT screening at a single time point
3. The proportion of participants found to have incidental renal findings (cysts, anatomical variants) on non-contrast CT scanning at a single time point
4. The proportion of participants with non-renal findings i.e. abdominal aortic aneurysms, pancreatic and liver lesions on non-contrast CT scanning at a single time point
5. The proportion of RCCs found on the upper pole of participants in T2 who did not have them in the T0 round, to estimate the incidence of RCC over sequential non-contrast LDCT scans

Previous secondary outcome measures:
1. The proportion of participants found to have an RCC measured using CT at a single time point
2. The stage distribution of RCC identified through non-contrast CT screening at a single time point
3. The proportion of participants found to have incidental renal findings (cysts, anatomical variants) on non-contrast CT scanning at a single time point
4. The proportion of participants with non-renal findings i.e. abdominal aortic aneurysms, pancreatic and liver lesions on non-contrast CT scanning at a single time point

Completion date
30/04/2023

Eligibility

Key inclusion criteria
The study is only open to participants of the Yorkshire Lung Screening Trial who are high risk for lung cancer as defined by one of the three criteria:
1. 30 pack year history of smoking and current smoker or quit within the last 15 years (USPSTF

criteria)
2, Lung cancer risk of ≥1.51% over 6 years as calculated by the PLCOM2012 score
3. Lung cancer risk of ≥5% over 5 years as calculated by the LLPv2. score)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
4019

Key exclusion criteria
1. Have undergone CT Thorax within the previous 12 months
2. Unable to provide informed consent to study
3. Unable to have a chest or abdominal non-contrast CT scan
4. Previous diagnosis of kidney cancer
5. Have undergone abdominal CT scan in previous 6 months

Date of first enrolment
12/04/2021

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James University Hospital
Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
In order to meet our ethical obligation to responsibly share data generated by clinical trials, YKST operates a transparent data sharing request process. Anonymous data will be available for request once the study has published the final proposed analyses. Researchers wishing to use the data will need to complete a Request for Data Sharing form describing a methodologically sound proposal. The form will need to include the objectives, what data are requested, timelines for use, intellectual property and publication rights, data release definition in the contract and participant informed consent etc. A Data Sharing Agreement from the Sponsor may also be required

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article		12/09/2024	25/09/2024	Yes	No
Protocol article		20/09/2022	27/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes