ISRCTN12706992 https://doi.org/10.1186/ISRCTN12706992

Pathology Artificial-Intelligence Clinical Evaluation Study

Submission date
24/09/2024

Recruitment status
No longer recruiting

Registration date
15/10/2024

Overall study status
Ongoing

Last Edited
26/09/2024

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Artificial intelligence (AI), particularly machine learning (ML), is set to revolutionize cancer research and clinical care by speeding up research, improving diagnostics, and enabling personalized treatment plans. This is especially promising for colorectal (CRC) adenocarcinoma, where specific algorithms have been developed. Digitizing pathology processes within the NHS enhances benefits for CRC patients, allowing pathologists to work remotely and collaboratively. The main benefits include improved workflow and the creation of teaching datasets for ML technology, leading to more reproducible and objective analyses with faster turnaround times. ML can alleviate the workload crisis in clinical pathology by flagging cases for further investigation and providing detailed analysis. Digital pathology represents the future, integrating ML into current care pathways to improve diagnostics and prognostics. This study aims to demonstrate that ML algorithms can run alongside routine pathology, providing timely diagnostic and prognostic information without delaying treatment decisions. It also seeks to evaluate the impact of these algorithms on clinical decision-making. Oxford-based research groups have developed ML algorithms to enhance treatment pathways for CRC patients, leveraging the digitization of clinical pathology to improve diagnostics and prognostication. The PACES study will explore how these algorithms can support or change clinical treatment decisions. As AI in the form of ML is a new and untested healthcare technology, this study aims to determine its use by clinicians and integration into existing care pathways with accredited algorithms. PACES is a clinical utility study focused on care pathways and the potential impact on treatment decisions. To avoid bias, clinicians will receive algorithm results only after making treatment decisions.

Who can participate?
NHS patients aged 18 years old and over with clinical suspicion or confirmed diagnosis of colorectal adenocarcinoma of any stage scheduled for anti-cancer treatment

What does the study involve?
Pseudonymous digital images of histological slides generated as part of routine NHS care will be obtained with participant consent. Images will then be run through three different machine learning algorithms; different algorithm outputs relate to different recommendations in colorectal cancer diagnosis and/or treatment. After a decision on real-life diagnosis/treatment

has been made by the participant's medical team, algorithm outputs will be sent to clinicians who will be asked if their recommendation of diagnosis/treatment would have changed if they had received algorithm outputs earlier (e.g., during MDT meetings).

What are the possible benefits and risks of participating?
Participants will not directly benefit from taking part, however, information gathered from participants in this study may help others with similar conditions in the future. Additionally, data from this study will help us learn how new technologies could be used in real-world clinical settings to help doctors and their patients make better, personalised decisions on cancer treatment in the future. Overall, participation in this study is considered very low risk, as all procedures follow well-established standard NHS processes.

Where is the study run from?
The University of Oxford and Oxford University Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
February 2024 to October 2026

Who is funding the study?
The University of Oxford CRUK Centre and Oxford Cancer Biomarkers Ltd.

Who is the main contact?
The study team at: paces@medsci.ox.ac.uk

Study website
https://www.cancer.ox.ac.uk/research#projects

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333259

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PID17656

Study information

Scientific Title
A clinical utility study investigating the integration of machine learning algorithms into the colorectal cancer care pathway, from histopathology to the clinical multidisciplinary team

Acronym
PACES

Study objectives
Including outputs from machine-learning algorithms during colorectal cancer multidisciplinary team meetings is beneficial to decisions regarding diagnosis and/or treatment recommendations.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/07/2024, South Central - Oxford C Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048144; oxfordc.rec@hra.nhs.uk), ref: 24/SC/0165

Study design
Clinical utility study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Other, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Pseudonymous digital images of histological slides generated as part of routine NHS care will be obtained with participant consent. Images will then be run through three different machine learning algorithms, different algorithm outputs relate to different recommendations in colorectal cancer diagnosis and/or treatment. After a decision on real-life diagnosis/treatment has been made by the participant's medical team, algorithm outputs will be sent to clinicians who will be asked if their recommendation of diagnosis/treatment would have changed if they would have received algorithm outputs earlier (e.g., during MDT meetings).

Intervention Type
Other

Primary outcome measure
The efficacy of integrating machine learning algorithms into the digital pathology and clinical decision pathway for CRC will be measured using questionnaire data obtained from clinical care and pathologist teams after a decision on real-world treatment has been made

Secondary outcome measures
Conclusions on whether algorithm analyses would have changed real-world treatment recommendations will be derived from percentage changes of theoretical treatment recommendations captured from questionnaires completed by clinical care and pathologist teams at the end of the study

Overall study start date
01/02/2024

Completion date
01/10/2026

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Clinical suspicion or confirmed diagnosis of colorectal adenocarcinoma of any stage
2.1. Participant is scheduled for anti-cancer treatment including one or more of the:

2.1.1. Resection of primary tumour or metastatic disease
2.1.2. Systemic anti-cancer therapy including chemotherapy, biological therapy or immunotherapy in either the neoadjuvant, adjuvant or metastatic settings
2.1.3. Local radiotherapy or Stereotactic Ablative Radiotherapy (SABR) tumour ablative therapies
3. The patient is scheduled for palliative care only
4. Age >18 years
5. The participant is willing to comply with all study requirements

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Both

Target number of participants
170

Key exclusion criteria
1. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.
2. Treatment with chemoradiotherapy prior to diagnostic biopsy related to the cancer under study in the past 12 months.

Date of first enrolment
01/10/2024

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital

Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office, Boundary Brook House, Churchill Drive, Headington
Oxford
England
United Kingdom
OX3 7GB
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rgea.sponsor@admin.ox.ac.uk

Sponsor type
University/education

Website
https://www.cancer.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
University of Oxford

Alternative Name(s)
University in Oxford, Oxford University, , Universitas Oxoniensis

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/10/2028

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?
Participant information sheet	version 2.0	18/06/2024	26/09/2024	No	Yes