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Examining the impacts of pathologists using the assistance of computer technology (artificial intelligence software) on the diagnosis of prostate cancer biopsies

Submission date
01/07/2022

Recruitment status
No longer recruiting

Registration date
25/08/2022

Overall study status
Completed

Last Edited
23/07/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Prostate cancer is currently diagnosed by histopathologists who expertly examine thin slices of tissue that are prepared as glass slides and viewed under a microscope. The pathologists assess whether cancer is present, how aggressive it is, and how much is present so that treatment decisions can be taken for patients. However, there are increasing volumes of cases and cases are becoming more complex; there is also a shortage of specialised pathologists that is especially felt in the UK and Europe. By using digital images and with the assistance of artificial intelligence (AI)-based software, pathologists can do routine screening, grading and measuring with assistance to enable a safe and more efficient service. Paige Prostate is a software device that has regulatory approval for clinical use and is the first-ever AI-based software to receive FDA approval in pathology. The aim of this study is to use the Paige Prostate cancer detection and quantification and grading software to assist prostate biopsy reporting for patients across three hospitals in England (UK) and compare the performance of pathologists either using or not using Paige Prostate.

Who can participate?
Patients undergoing prostate biopsy as part of the standard diagnostic pathway at the participating hospitals

What does the study involve?
This is a histopathologist-led study conceived with patient representatives that is conducted at hospital pathology laboratories in a real clinical setting as part of the standard practice for diagnosing prostate cancer. This study examines if and how pathologists' diagnoses are changed when they see and use the information made available by Paige Prostate. The outputs of Paige Prostate include visual overlays that draw the attention of pathologists to areas of prostate biopsy tissue that are suspicious for harbouring cancer. Paige Prostate also displays the grade, length and quantity of tumour as numerical outputs. Pathologists will be able to see and view the outputs of Paige Prostate before signing out cases and reporting results to patients. If

pathologists have changed their original diagnoses due to using Paige Prostate, then these discrepancies will be examined further with additional tests and additional review before final case authorisation. The impact of these discrepancies on patient treatment scenarios as well as costs to the health system will be modelled to assess if and how Paige Prostate can improve the efficiency and quality of prostate biopsy diagnosis. The clinician experience will also be surveyed and resource efficiency measured by studying the impact of routine use of Paige Prostate compared to current resources used. This study will also create guidelines and standards for best practice to safely introduce AI assistance into pathology diagnosis, both professional guidelines as well as patient-led guidelines from patient and public representatives.

What are the possible benefits and risks of participating?
Paige Prostate is not a replacement for the pathologist but rather provides additional information to help pathologists. Pathologists determine and authorise the diagnosis of all cases and can agree or disagree with the findings of Paige Prostate. This is a guiding principle of the study and was formed together with patient representatives and the clinical study team. There are no risks to patients in this study as they receive their full current standard of care with the addition of a market-authorised and clinically validated system in the hands of experts taking all decisions.

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

When is the study starting and how long is it expected to run for?
September 2021 to February 2024

Who is funding the study?
Accelerative Access Collaborative and NHSx through a Phase 4 AI in Health and Care Award (UK)

Who is the main contact?
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Protocol serial number
AI_AWARD02269

Study information

Scientific Title
Driving improvements for prostate biopsy patients using Paige Prostate AI software to determine the benefits of pathologist-led diagnosis before and after the deployment of AI assistance (ARTICULATE PRO)

Acronym
ARTICULATE PRO

Study objectives
Paige Prostate both in standalone performance tests and as an assistance to pathologists has been demonstrated to improve the accuracy of the diagnosis of prostate cancer and to save histopathologists' time in diagnosing cancerous tissue in prostate core needle biopsy digital slide images. This study will examine prospectively in a real-world setting on patients as part of the standard of care the impact of Paige Prostate on diagnostic decision-making, resource use, clinician acceptance and patient treatment recommendations and patient experiences.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study is an Evaluation of Clinical Care (Service Evaluation) and is neither research nor a clinical trial as concluded by the Study Sponsor, and the University of Oxford Clinical Trials and Research Governance Study Classification Committee.

Primary study design
Observational

Study design
Multicentre observational prospective study on consecutive cohorts

Study type(s)
Diagnostic

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

Interventions
Digital images of histopathology slides prepared from prostate core needle biopsy tissue for primary diagnosis are viewed by specialist histopathologists according to the standard diagnostic pathway for prostate cancer. The outputs of the Paige Prostate medical device software are made available to the pathologists and amendments to diagnostic parameters of prostate biopsy cases and potential impact on patients' clinical management determined at MDT due to Paige Prostate assistance, including prostate cancer/ASAP (suspicious) detection, Gleason grade 4 identification and tumour burden measurements.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Paige Prostate

Primary outcome(s)

Immediate changes to diagnostic reports of prostate biopsy cases and the corresponding immediate changes in patients' clinical management due to the use of Paige Prostate assistance, as measured by cancer/ASAP identification, Gleason grade 4 identification, tumour burden including length, number of involved cores, treatment pathway recommendation as determined by a multidisciplinary team (MDT).

Key secondary outcome(s)
1. Impact of Paige Prostate on resource utilisation, as measured by time and tests required for pathologists to review prostate biopsy cases and make clinical recommendations at MDT, and as measured by labour landscape in terms of staff and workloads. Comparison of resource utilisation across two separate consecutive cohorts, one without Paige Prostate, and one after Paige Prostate deployment.
2. Impact of Paige Prostate on patient management, as modeled using health economics and current patient pathways, their co-morbidities and their costs, and the diagnostic discrepancies comparing unassisted and assisted diagnoses over the lifetime of a prostate cancer patient receiving biopsy.
3. Impact of Paige Prostate on the experiences of histopathologists, urologists and patients, as measured by survey and qualitative methods on prostate biopsy diagnosis and treatment selection challenges, comparing standard of care immediate experience at baseline to experience ascertained as pathologists go through the learning curve of adopting AI over the course of this study.

Completion date
29/02/2024

Eligibility

Key inclusion criteria
All patients undergoing prostate biopsy for suspected prostate cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. Patients who have opted out of clinical care via the existing 'consent to examination or treatment policy'
2. Non-prostate biopsy tissue

Date of first enrolment
28/04/2022

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
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Study participating centre
University Hospital Coventry
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Study participating centre
Southmead Hospital
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Accelerated Access Collaborative, NHSx, Artificial Intelligence in Health & Care Award

Results and Publications

Individual participant data (IPD) sharing plan

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?
Results article		22/05/2026	23/07/2026	Yes	No
Interim results article		13/05/2022	01/07/2022	Yes	No
Participant information sheet		26/04/2022	21/07/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes