

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/08/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/08/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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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Study website

<https://www.nds.ox.ac.uk/research/verrill-pathology-group/articulate-pro>

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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.

Study design

Multicentre observational prospective study on consecutive cohorts

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

See trial outputs table

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 measure

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).

Secondary outcome measures

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.

Overall study start date

01/09/2021

Completion date

29/02/2024

Eligibility

Key inclusion criteria

All patients undergoing prostate biopsy for suspected prostate cancer

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

1500

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

England

United Kingdom

Study participating centre

John Radcliffe Hospital

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

Study participating centre

University Hospital Coventry

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Sponsor information

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Sponsor type
University/education

Website
<http://www.ox.ac.uk/>

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

Publication and dissemination plan

- 1. Planned primary publication in high-impact peer-reviewed journal
- 2. Supporting secondary publications
- 3. Public-facing dissemination also planned including news announcements, patient-facing content created in collaboration with Prostate Cancer UK, and professional symposia

Intention to publish date

01/08/2024

Individual participant data (IPD) sharing plan

Data management plan for this study as part of Clinical Care Evaluation in development. Data sharing statement to 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?
Interim results article		13/05/2022	01/07/2022	Yes	No
Participant information sheet		26/04/2022	21/07/2022	No	Yes