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The Imperial Prostate 9 - Approaches To Long-term Active Surveillance: Regular MRI scans versus standard of care (IP9-ATLAS) randomised controlled trial

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ABSTRACT

Introduction and objectives: Active surveillance is heterogenous using combinations of prostate specific antigen (PSA), digital rectal exam (DRE), magnetic resonance imaging (MRI) and biopsy. Using serial prostate MRI scans during active surveillance to inform when to conduct repeat biopsies might be effective to balance the burden of testing and detecting cancer progression early.

IP9-ATLAS aims to determine whether regular MRI scans during active surveillance, compared to current standard of care (clinically-indicated MRI scans), will improve detection of cancer progression over 5 years.

Methods: IP9-ATLAS is a prospective, multi-centre RCT including patients with a histological diagnosis of Grade Group 1 or 2 disease on active surveillance. It compares UK NICE-defined standard of care (regular PSA and DRE when indicated with clinically-guided use of repeat MRI and biopsy), against the intervention arm (regular PSA and regular prostate MRI scans without intravenous contrast medium (i.e. biparametric), planned yearly for patients with an MRI-visible cancer lesion or Grade Group 2 cancer and every 2 years for all other patients). An internal pilot will determine the feasibility of the trial. 1263 patients will be recruited. Ethics committee approval has been granted by the Health Research Authority Research Ethics Committee Wales.

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Results: The primary outcome is cancer progression rate, defined as higher risk cancer on biopsy (Grade Group ≥3) or a higher stage (≥T3 or ≥ N or ≥ M1) over 5 years. Secondary outcomes will include treatment rates without progression, adverse events, cost-effectiveness and functional outcomes. Recruitment started in May 2024 and is due to complete in June 2027, with follow-up until 2032. The trial is registered with the ISRCTN and Clinical Trials.gov (ISRCTN11447662 / NCT06280781).
Conclusion: IP9-ATLAS aims to provide robust level 1 comparative data to improve active surveillance protocols and change practice.

1. Introduction

Active surveillance uptake varies internationally, with 75–95% of low-risk prostate cancers monitored in Europe, and approximately 50% in America [1]. Over the past decade, active surveillance has increasingly been employed, with for instance, a rise from 26.5% in 2014 to 59.6% in 2021 in the USA [2]. In the UK, approximately 15% (about 7600) of the 50,000 patients newly diagnosed with prostate cancer every year choose active surveillance as opposed to radical therapy (radiotherapy or immediate surgery) [3–5]. Upto 70–80% of these patients will have low-risk disease, considered biologically indolent, and 20–30% have medium risk prostate cancer [6]. These types of cancers progress slowly [5]. Immediate treatment does not improve cancer-specific survival over 15 years [7] but does cause significant urinary, sexual and bowel-related side effects that are detrimental to quality of life [8,9]. A recent discrete choice experiment (COMPARE) study of 740 newly diagnosed patients with localised prostate cancer showed that patients were willing to prioritise active surveillance in order to avoid the impacts of radical therapy, even accepting a slight increase in risk of reduced cancer control [8].

Despite the slow progression of these types of cancer, 25–34% will progress to higher risk cancer over 5 years and subsequently need treatment [10–14]. Currently, ProtecT, the largest randomised controlled trial (RCT) comparing Active Monitoring (a precursor to current active surveillance protocols) to immediate treatment demonstrated that patients in the active monitoring arm had higher rates of clinical progression (25.9% vs. 10.5% vs 11% respectively) and cancer metastasis (9.4% vs. 4.7% and 5.0% respectively) when compared to radical surgery or radiotherapy [7]. Metastasis free survival has been demonstrated as a validated surrogate for cancer related mortality [15]. Critically, the ProtecT trial recruited its patients prior to MRI being introduced in the prostate cancer diagnostic pathway, leading to higher rates of cancer misclassification with more significant cancers being undetected. Patients were also randomised into the three arms regardless of Gleason Grade and 33.7% of the whole cohort had intermediate (24.1%) or high-risk (9.6%) prostate cancer. The higher metastatic rate observed in the monitoring group could reflect these patients, who are naturally at a higher risk of cancer progression.

1.1. Current standard of care in active surveillance

The current UK National Institute for Health and Care Excellence (NICE) guidelines recommend Prostate Specific Antigen (PSA) testing every 3–4 months for the first year and every 6 months thereafter. A digital rectal examination (DRE) is recommended every 12 months. At 1 year, they advise an MRI and biopsy if there was no baseline pre-biopsy MRI. After 12 months, PSA and DRE are recommended with further biopsy if the PSA increases or if there is a new prostate nodule upon DRE [16].

There are several issues related to the current pathway. Firstly, PSA and DRE changes can be inaccurate in detecting cancer progression. As a result, many centres carry out regular biopsies every 1–2 years [4]. However, standalone biopsies are also inaccurate as suspicious areas are not well-visualised on ultrasound. In addition, side effects of biopsies include infection, sepsis, bleeding, and pain [17]. For instance, studies have shown sepsis rates of up to 2.7% for transperineal biopsies and 2.6% for transrectal biopsies [18–20]. Scarring around the prostate from repeat biopsy might make subsequent surgical treatment more difficult [21]. Patients are also unlikely to agree to further biopsies when complications occur [22]. In addition to this, 10–43% of patients decide to have radical treatment despite lack of objective evidence of cancer progression. Some of the reasons are anxiety related to living with cancer [23] or due to the repeat biopsies and burden of tests [24,25].

Furthermore, there are no guidelines defining what types of changes should trigger further investigation. Metrics such as PSA doubling time or PSA velocity are often used. However, the existing literature demonstrates that PSA doubling time changes are not, and PSA velocity only weakly, associated with cancer progression [26–31]. The sensitivity and specificity of PSA kinetics in predicting progression on transrectal systematic biopsy has been shown to be 40–59% and 44–78% respectively [28].

Concerning the DRE, although there is some limited evidence that it may be useful in predicting progression [32], NICE nevertheless has recommended its use due to its inclusion in most active surveillance studies, despite the scarcity of data supporting this.

The current European Association of Urology Guidelines (2024) are similar to the current NICE guidelines and state that one should:

- Base the strategy of active surveillance on a strict protocol including DRE (at least once yearly), PSA (at least once every six months) and repeated biopsy every 2 to 3 years.
- Perform MRI and repeat biopsy if PSA is rising (PSA-doubling time < 3 years).

1.2. Regular MRI in active surveillance

Pivotal studies have changed current recommendations for MRI in the diagnosis of prostate cancer [33,34]. Following this, it has been demonstrated that regular prostate MRI scans with targeted biopsies to areas of suspicion are accurate in ruling-out and detecting progression [35,36].

One of the existing RCTs looking at MRI in active surveillance is the ASIST trial, where patients were randomised between systematic biopsy or MRI with targeted and systematic biopsies 9 to 13 months after the initial diagnosis of low-risk prostate cancer. Although the initial data did not show a difference in upgrading between the 2 groups [37], the 2-year follow-up data showed 50% fewer active surveillance failures in the confirmatory MRI group as well as a lower rate of grade progression [10]. Critically, patients were recruited prior to the use of MRI for diagnosis, so baseline misclassification was often picked up in the follow-up MRIs, with a progression rate that was based on this initial under-grading rather than the true cancer progression rate. The ROMAS RCT also evaluated the role of an early confirmatory MRI rather than a follow-up MRI [38].

Several systematic reviews evaluating the role of MRI in active surveillance have shown pooled sensitivities of 59–81% and specificity between 75 and 81% [11–14,39]. Negative Predictive Values (NPVs) were in the range of 75–94% indicating that patients could avoid biopsies if the MRI showed no progression. However, most of the cohorts included were retrospective, had heterogeneous inclusion and follow-up protocols, and similarly to the RCTs, did not use MRI to diagnose prostate cancer, leading to initial under-detection of significant prostate

cancer.

In an effort to standardise interpretation and reporting of follow-up MRIs for active surveillance patients, the Prostate Cancer Radiological Estimation of Change in Sequential Evaluation (PRECISE) recommendations were developed during an international consortium meeting, with a 5-point score to assess the likelihood of radiological cancer progression [40], which was recently updated [41]. Regression on MRI is indicated by a PRECISE score of 1 or 2 and a PRECISE score of 3 (divided into non-visible and visible) indicates radiological stability. A PRECISE score of 4 or 5 is suspicious for radiological progression [42].

The PRECISE score has, since its creation, been validated by several groups and a recent UK publication suggested that the score was useful for predicting cancer progression and found a sensitivity of 74.1%, a specificity of 94.7%, a Positive Predictive Value (PPV) of 90.9% and an NPV of 83.7%, with an Area Under the Curve (AUC) of 0.84 [43], which is similar to what other authors have found [44,45].

In the existing literature, robust level 1 evidence regarding MRI in active surveillance is lacking. An RCT comparing the standard of care (SOC) using the current NICE recommendations for active surveillance against the use of regular MRI scans during follow-up is needed to change medical practice.

1.3. IP-9 ATLAS hypothesis

We hypothesise that the use of regular MRI scans in patients managed using active surveillance will lead to an improved detection of cancer progression over 5 years when compared to the current standard of care. The primary and secondary objectives of the trial are highlighted in Table 1.

2. Methods and analysis

2.1. Study design and dates

IP9-ATLAS is a multi-centre, RCT allocating patients in a 1:1 ratio to either regular MRI scans or the current UK NICE defined SOC, with embedded trial and model based economic evaluation.

Study recruitment commenced in May 2024, with an embedded assessment of feasibility of recruitment completed after 12 months of recruitment to the pilot. Planned main phase recruitment and follow-up are expected to be completed by 2027 and 2032, respectively.

2.2. Patient and public involvement (PPI)

Two patient-involvement focus groups were held with 6–7 patients who were on active surveillance around the UK to determine initial patient acceptability and gauge important opinions on the proposed study design. Three patient and public involvement representatives are co-applicants, will attend research meetings and lead the regular focus groups. They will continue to be involved throughout the duration of the trial, in order to share the trial's concept, conduct and results. A PPI focus group will meet to review patient material and recruitment strategies before pilot start and every 6–12 months during the study to help make changes if required.

2.3. Study population

Patients with a histological diagnosis of localised prostate cancer in the 9 months prior to the screening visit who have chosen active surveillance. The timeframe was chosen after discussions with our focus groups, in order to include patients diagnosed as close to 1 year as possible prior to screening to maximise participation.

Table 1
IP9-ATLAS primary and secondary outcomes, study endpoints and outcomes.

Objectives	Endpoint Measures	Outcome Measures
Embedded pilot		
Study feasibility	Recruitment	Recruitment rate: the percentage of approached patients who consent to participate per month
	Randomisation	Randomisation rate: the percentage of patients who have consented and have been allocated to each arm of the trial
Primary Objective		
To improve the detection of cancer progression over 5 years with the use of regular MRI scans compared to the current NICE defined strategy, in patients on active surveillance	Prostate cancer progression rates	Prostate cancer progression rates defined on: - Biopsy: grade progression to ≥GG3 or detection of intraductal cancer or lymphovascular invasion. Cribriform pattern is not a factor for progression. - Staging: extracapsular progression, lymph node involvement, distant metastasis demonstrated on MRI, CT, bone-scan or PET scans, as determined by the local multidisciplinary cancer team
	Time to cancer progression	Time from baseline to cancer progression
Secondary Objectives		
Cost-effectiveness	Cost-effectiveness of revising the prostate cancer active surveillance protocol incorporating regular MRI scans	Data on costs and resource utilisation for cost-effectiveness analysis using an incremental cost effectiveness ratio (ICER)
Compliance	Compliance to allocated surveillance strategy	Proportion of patients having each test (PSA, rectal exam, MRI) at each allocated time point in each trial arm Proportion of patients agreeing to a biopsy when clinically recommended
Patient reported outcome measures (PROMs), cancer-related anxiety, quality of life	Impact on urinary, erectile and bowel function (EPIC), cancer-related anxiety (HADS), and overall health-related quality of life (EQ-5D-5L)	Validated PROMs collected annually with comparison between baseline and follow-up questionnaires scores for urinary, erectile and bowel function (EPIC questionnaire), cancer-related anxiety (HADS), overall health-related quality of life questionnaire (EQ-5D-5L) and quality-adjusted life years
Biopsies in follow-up	Proportion of patients requiring biopsy during their follow-up	Proportion of patients requiring biopsy compared to total number of patients in each arm
Side-effects and complications	MRI and biopsy-related adverse events during the study follow-up in both arms	Rates of MRI and biopsy-related adverse events and serious adverse events in patients who have had the tests
Treatments during follow-up	Patients treated for prostate cancer	Proportion of patients treated for prostate cancer compared to all the patients in the trial in each arm
	Types of treatment in patients with or without	Type of treatment for

(continued on next page)

Table 1 (*continued*)

Objectives	Endpoint Measures	Outcome Measures
	progression	patients who progress and those who do not progress (prostatectomy, radiotherapy, brachytherapy, focal therapy)
	Types of treatment in patients for lower urinary tract symptoms (LUTS)	Use of systemic therapy and type in patients who do and do not progress
		Type of treatment for LUTS for patients who do and do not progress

2.4. Patient eligibility

2.4.1. Inclusion criteria

1. Patients with a prostate (either cis-male gender or trans-female gender with no prior androgen deprivation hormone use at all)
2. Over or equal to 18 years of age (no upper limit)
3. Diagnosed with prostate cancer within 9 months of screening visit
4. Diagnostic systematic biopsies +/− targeted biopsies
5. A histological diagnosis of localised prostate cancer
6. Gleason Grade Group 3 + 3 = 6 and 3 + 4 = 7 (Grade Groups 1 (GG1) and 2 (GG2) respectively)
7. Patient who has chosen active surveillance as their management option

2.4.2. Exclusion criteria

1. Patients on active surveillance >9 months prior to consent / screening date
2. Any absolute contraindication to MRI or gadolinium contrast
3. Previous hip replacement to both hips
4. Contraindication to performing a biopsy guided by transrectal ultrasound probe

2.5. Procedures and measurements

Patients randomised into the standard of care active surveillance arm will have a 3-monthly PSA test and annual DRE if clinically indicated over the course of the 5-year follow-up. An MRI without intravenous contrast medium (i.e. biparametric) will be carried out at 12 months if there is no MRI at diagnosis. If at any point, cancer progression is suspected (through increase in PSA or change in DRE), an MRI and a biopsy will be recommended. A biopsy can be triggered if any of the examinations (PSA doubling time, DRE or MRI) demonstrate a suspicion for cancer progression.

Concerning the intervention arm, patients will have a 6-monthly PSA test and will have 1–2 yearly biparametric MRI scans. A patient with a visible MRI lesion or prostate cancer classified as GG2 will have a yearly MRI, whereas a patient with no visible MRI lesion and GG1 prostate cancer will have an MRI every 2 years (years 1, 3, 5). This stratification has been determined by existing knowledge that the progression rate is higher in patients with MRI visible lesions and Gleason 3 + 4 on baseline biopsy [46,47]. The MRI will last about 15 min and does not require gadolinium contrast injection. Targeted biopsies will be done if the MRI PRECISE score is >/= 4.

- Prostate specific antigen (PSA): testing will be carried out as per local standards by the GP or in hospital. These blood tests are part of routine care and no additional blood is taken for the purpose of this study in any participant.
- MRI: a study-specific standard operating procedure (SOP) will be used. 1.5 or 3.0 Tesla scanners can be used. A quality review of MRI scans from all centres prior to recruitment will be performed by our lead radiology co-applicants alongside the NCITA imaging quality assurance / quality control process. Radiologists will also be required to report the PI-QUAL V2 score, a 3-point scoring system designed to standardise the reporting related to the quality of the MRI scans [48]. Patient preparation will follow up-to-date guidance at the time of study set-up. For quality control, standardisation meetings will be held prior to recruitment and use at least the NCITA MR Core Lab's basic level of service. Reporting and interpretation will be standardised using the latest version of the PRECISE scoring system [41]. Reporters will be accredited by validated courses and a minimum of 5% of MRI scans will be double reported to evaluate inter-observer variability.
- Biopsy: centres can use local anaesthetic, sedation or general anaesthesia. Biopsies can be done either via the transperineal or transrectal route, and operators can use visual-registration or image-fusion targeting. All this information must be recorded. A biopsy SOP will be used and targeted biopsies will be carried out first, with 4–6 cores per target. The systematic biopsy protocol used will be recorded. Biopsy will be recommended when there is a change in MRI or if there is a consistent rise in PSA over 3 readings that is concerning for progression, and a PSA doubling time < 3 years, even if there are no MRI changes and other factors (eg prostatitis, infection) have been ruled out. Quality assurance will be conducting during monitoring visits and the biopsy strategy will be recorded in the database. Deviations from the declared systematic biopsy strategy or the emergence of different biopsy strategies between the two pathways will be raised during Trial Management Group meetings and a centre may be asked to pause or discontinue recruitment.
- Histology: the following aspects will be reported according to the Royal College of Pathology (UK) guidance (2016): number of biopsies, number positive for cancer, core length in mm, cancer presence, maximum cancer core length in mm (where continuous and discontinuous numbers are given, for the purpose of analysis, the continuous number will be used), primary, secondary and highest Gleason grade, percent pattern 4 and presence of cribriform pattern when Gleason 3 + 4, perineural invasion / lymphovascular invasion / intraductal components / neuroendocrine differentiation and other features (high grade prostatic intraepithelial neoplasia / atypical acini/ inflammation / atrophy).
- Validated PROMs: all patients will complete the Expanded Prostate Cancer Index (EPIC) for the Urinary, Bowel and Erectile domains and the EuroQol (EQ-5D-5L) which will be used in the study as a generic measure of health-related quality of life which can be linked to public preferences [49]. Patients undergoing biopsy will be asked to self-report pain and discomfort immediately after and 7 days after biopsy on a 4-point Likert-type scale (none, mild, moderate, severe). Specific related complications (fever, flu-like shivers, pain, haematuria, haematochezia, haematospermia) will be self-reported at 35 to 90 days after prostate biopsy as absent or present. Each symptom will be scored to a degree of “problem” (none, minor, moderate, major). Concerning MRI, a questionnaire on MRI related side-effects will be given to all patients to be completed after the MRI but before biopsy (if needed). Patients will also be asked to fill out a cancer-related anxiety questionnaire (Hospital Anxiety and Depression Scale (HADS)).

2.6. Patient identification

All patients eligible for the study will be initially approached by their clinical team and patient information sheets are sent to them. Further contact and explanations are provided by the local research team if the patients are interested. Remote electronic consent will be facilitated. Patients will have the opportunity to discuss with the trial investigator

prior to consenting, either in person or via a telephone conversation. Written informed consent will be obtained before any study related procedures.

2.7. Randomisation

Patients will be allocated in a 1:1 ratio to either the current NICE defined standard or regular MRI scans. Randomisation will be blocked (random block size) and stratified by MRI visibility of lesion (3 categories, 1) no visible lesion, 2) diffuse changes, 3) discrete visible lesion), cancer Grade Group (GG1, GG2) and time since diagnosis. The study allocation will not be blinded to patients or physicians.

2.8. Study endpoints and outcome measures

Primary and secondary endpoints for the study as well as study outcome measures are presented in Table 1.

An economic evaluation will estimate the long-term health outcomes and NHS costs of MRI-based active surveillance compared to the current standard of care, aiming to determine if the MRI-based strategy represents good value for money to the NHS. Costs and health outcomes associated with the interventions will be collected over the trial period and extrapolated over a patient's lifetime. This will involve developing a decision-analytic model to predict long-term quality-adjusted life expectancy and NHS costs, based on the observed differences in the trial's primary and secondary endpoints. Long-term extrapolation may also draw on other epidemiological and clinical evidence from published sources. The evaluation will generate an incremental cost-effectiveness ratio (ICER) by comparing the differences in costs and quality-adjusted life years (QALYs) between the two strategies, which will then be compared to the opportunity cost of funding the intervention in the NHS. The study will also assess the practical feasibility of implementing MRI-based surveillance, considering potential capacity constraints within the healthcare system.

2.9. Visit schedule

The visit schedule for IP9-ATLAS participants is detailed in Table 2.

2.10. Follow-up

With regards to the standard care arm, the follow-up visits are defined by the SOP. No additional visits are required for the study.

Concerning the intervention arm, patients will undergo the follow-up addressed in the procedures and measurements section as well as in Table 2.

Concerning longer term follow-up, all patients will be consented for linkage to national databases and clinical outcomes can be collected after study end on use of subsequent tests and treatments as well as adverse events and survival.

Participants may be discontinued from the study at their request, in case of adverse events, or if the investigator considers that a participant's health will be compromised due to adverse events or concomitant illness that develop after entering the study. Withdrawal from the study can take place if the patient requests it or if they are lost to follow-up.

2.11. Adverse events

Adverse events (AEs) and serious adverse events (SAEs) will be recorded throughout the study. The severity and causality of the AEs will be investigated. AEs and SAEs will be followed up according to local practice until the event has stabilised, resolved or until the follow-up visit, whichever is sooner.

Table 2
Visit schedule for IP9-ATLAS participants.

		Screening	Consent					
Visit			1	2	3	4	5	6
Month		0	Up to 9 months from biopsy date	12	24	36	48	60
	All arms							
	Informed consent		X					
	Inclusion and exclusion criteria	X						
	Demographics		X					
	Targeted medical history *(Prostate MRI and biopsy details, current use of 5-alpha reductive inhibitors, use of testosterone supplementation or androgen suppression medication, family history of prostate cancer, ethnicity)*	X						
	Patient questionnaires		X	X	X	X	X	X
	Standard care arm							
	PSA blood tests (every 3 months for 5 years)			X	X	X	X	X
	PSA doubling time (every 6 months, 3 readings)			X	X	X	X	X
	Digital rectal examination (if clinically indicated)			X	X	X	X	X
	Biparametric MRI and outcomes			X (if no MRI prior to diagnosis or if clinically indicated)	If clinically indicated			
	Biopsy and results			If clinically indicated				
	Further treatment for prostate cancer			Can be due to progression or patient choice				
	Intervention arm							
	PSA blood tests (every 6 months for 5 years)			X	X	X	X	X
	PSA doubling time (every year, 3 readings)			X	X	X	X	X
	Biparametric surveillance MRI							
	- Visible MRI (discrete PIRADS 3, 4, 5) lesion OR GG2			X	X	X	X	X
	- No visible MRI lesion AND GG1			X		X		X
	- Diffuse PIRADS 3 MRI lesion AND GG1							
	Biopsy and results			If clinically indicated (if MRI PRECISE score >/= 4 or PSA doubling time </= 3 years)				
	Further treatment for prostate cancer			Can be due to progression or patient choice				
	Further treatment for lower urinary tract symptoms			Drug treatment or physical / operative interventions for LUTS				

2.12. Statistical analyses and sample size calculation

Based on the notion that 25% of the study population are assumed to develop cancer progression by 5 years, of which the current NICE defined strategy detects 50% of these progressive cancers, and that regular MRI will detect 75%, 1200 participants are required to have 90% power to detect a difference in time to progression between the two groups, using the log-rank test (two-sided alpha = 0.05) and assuming 3 years of recruitment and 5 years minimum of follow-up. Allowing for an expected 5% loss to follow-up over 5 years, 1263 participants will be randomised.

2.13. Embedded feasibility and pilot

We are seeking to determine whether recruitment and randomisation of patients managed by active surveillance is feasible within the first 12 months of the study. The aim is to recruit 216 patients from 12 centres, with approximately 5–7 eligible patients per month in each centre. In our 12-month internal pilot, we estimate a recruitment rate of 25% of patients from the eligible pool.

2.14. Data monitoring and archiving

At the screening visit, patients will be asked to give consent for identifiable data to be linked to national databases (Office for National Statistics (ONS) and Hospital Episode Statistics (HES)). The identifiable fields (NHS number) required for linkage will be encrypted using a one-way encryption algorithm. If patients are happy to give consent for their health status to be followed up over time, their identifiable data will be linked with records held by the NHS and maintained by the NHS information Centre and the NHS Central Register, or any applicable NHS information system. This will allow us to track what happens after the study finishes and observe if anyone gets further tests / investigations and treatment.

As prostate cancer is often a slow-growing disease, we will also ask patients to give consent for us to keep personal data stored or accessed for an additional 15 years on the NHSCR (National Health Service Care Register) so that data from national registries can be evaluated.

Patients will also be asked to consent whether they can be contacted by a member of the central / local research team within 15 years of signing the consent form to complete a questionnaire about their health status and quality of life.

An independent Trial Steering Committee (TSC) and Data and Ethics Monitoring Committee (DMEC) will meet twice a year.

All trial documentation, including that held at participating centres and trial coordinating centre, will be archived for a minimum of 10 years following the end of the study.

2.15. Ethical considerations

The trial was approved by the Health Research Authority (HRA) Research Ethics Committee Wales (REC) (reference number 23/WA/0323). The results will be submitted for publication in peer-reviewed journals. Annual progress reports will be submitted to the REC and the sponsor in accordance with local / national requirements and a Clinical Study Report summarising the study results will be prepared and submitted to the REC within a year of the end of study. The study is registered on a trial database ISRCTN (ISRCTN11447662) and clinicaltrials.gov (NCT06280781) in accordance with requirements of the International Committee of Medical Journal Editors (ICMJE) regulations.

2.16. Trial funding, organisation and administration

IP9-ATLAS is funded by The National Institute for Health and Care Research Health Technology Assessment Programme (NIHR HTA) (NIHR152027). The study will be monitored periodically by trial monitors to assess the progress of the study, verify adherence to the protocol, ICH GCP E6 guidelines and other national / international requirements and to review the completeness, accuracy and consistency of the data.

3. Discussion

IP9-ATLAS is a multi-centre, randomised controlled trial focusing on a research gap identified by the NICE research priorities [16] as well as the James Lind Alliance [50]. The hypothesis is that the use of regular MRI scans in patients managed using active surveillance will lead to an improved detection of cancer progression over 5 years when compared to the current NICE guided standard of care. The study will provide level 1 evidence on this matter.

The different principles behind the study are that the use of regular MRI scans in active surveillance will lead to a greater confidence in active surveillance for low and medium risk prostate cancer as this strategy is more likely to detect cancer progression earlier with fewer invasive biopsies [51].

Moreover, the number of patients with medium risk prostate cancer who could be managed by active surveillance in the future is increasing and this study could improve patient and physician confidence in active surveillance due to the use of a robust monitoring and follow-up strategy, allowing the detection of progression earlier on than current practice. If routine imaging follow-up proves to be a robust strategy for active surveillance follow-up, there will be fewer follow-up clinics, PSA tests and biopsies, thus reducing the burden on patients and healthcare systems.

4. Conclusion

IP9-ATLAS addresses an important research gap in active surveillance protocols and if the intervention arm is proven to provide improved cancer progression detection, this will have wide-reaching implications and have the potential to change the current standard of care.

CRediT authorship contribution statement

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Hashim U. Ahmed receives core funding from the UK NIHR Imperial BRC and Imperial NIHR/Cancer Research UK Experimental Cancer Medicine Centre (ECMC); receives research funding from the Wellcome Trust, UK Medical Research Council, Cancer Research UK, Prostate Cancer UK, UK NIHR, and Imperial Health Charity for trials in prostate cancer; is a paid proctor for HIFU (Sonablate Corp), cryotherapy (Boston Scientific), and Rezūm (Boston Scientific); is a paid scientific advisory board member for Francis Medical; has given lectures for Boston Scientific, Ipsen, and Janssen; has received funding to attend scientific conferences from Janssen; and has previously been on the medical advisory board for Janssen but not currently. Mark Emberton receives research support from the United Kingdom's national institute of Health Research (NIHR) UCLH/UCL Biomedical Research Centre. He acts as a consultant/advisor to the following companies: Sonacare Inc; Angiodynamics Inc; NINA Medical Inc; Albermarle Biosciences Ltd; Profound Medical Inc; and Insight MedBiotics Inc. Taimur T. Shah receives infrastructure support from the NIHR Imperial BRC and Imperial College ECMC; receives research funding from The Urology Foundation; receives consultation fees from Janssen and Varian; and has received funding to attend scientific conferences from Janssen and Sonablate Corp. Francesco Giganti reports consulting fees from DeepHealth, SpectraCure and Procept outside of the submitted work. He has received speaker fees from Bayer and Siemens. Martin J Connor receives funding from the UK NIHR, Prostate Cancer UK, University College London Hospitals (UCLH) Charity, Penguins Against Cancer Charty and The Urology Foundation (TUF) for his research into urological cancers.Matthias Winkler receives funding from The Urology Foundation for his research into prostate cancer. Alexander Light receives research funding from a UK National Institute for Heath and Care Research (NIHR) Doctoral Fellowship award (NIHR304727) and The Urology Foundation.

Data availability

No data was used for the research described in the article.

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