ISRCTN17215075 https://doi.org/10.1186/ISRCTN17215075

A large clinical trial testing different combinations of hormone treatments, with or without chemotherapy called docetaxel, in men with advanced prostate cancer whose prostate-specific antigen levels haven't dropped enough after 6 months of treatment

Submission date 18/11/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 14/01/2026	**Overall study status** Ongoing	
Last Edited 29/01/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Prostate cancer is incurable when it has spread to other parts of the body (called metastatic prostate cancer). Metastatic prostate cancer is initially managed with hormonal treatments. The most common first treatment option used for men in the UK is hormonal injections (androgen deprivation therapy, ADT) combined with hormonal tablets (an androgen receptor targeted agent, ARTA), known as a doublet therapy.

A blood test for a protein called prostate-specific antigen (PSA) is routinely used for monitoring patients to check whether their prostate cancer is responding to treatment. Almost all men have a reduction in their PSA result after starting their treatment. However, how far the PSA falls after treatment starts is a strong indicator of longer-term outcomes. Multiple studies have shown that if the PSA falls, but still remains above 0.2 ng/ml, after about 6 months of treatment with hormones, then the outcomes (such as survival) tend to be worse.

This clinical trial, called INTENSIFY, is for men with metastatic hormone-sensitive prostate cancer who have a PSA that remains above 0.2 ng/ml after 6 months of hormonal treatment. We will test whether they survive longer if we add chemotherapy to their treatment earlier than otherwise planned.

Who can participate?

Patients with prostate cancer, where the PSA falls but still remains above 0.2 ng/ml after 6 months of doublet hormonal therapy

What does the study involve?

Patients who choose to take part will be randomly selected to receive one of two possible treatment options:

1. Standard of care treatment: continue doublet hormonal therapy (ADT +ARTA)
2. Experimental treatment: continue doublet hormonal therapy plus chemotherapy
Chemotherapy will be with a drug called docetaxel given through a drip at the hospital outpatient treatment unit every 3 weeks for up to six treatments. This is a chemotherapy drug that has been used to treat different cancers for many years, including prostate cancer.

What are the possible benefits and risks of participating?
INTENSIFY will benefit patients who have metastatic prostate cancer and find themselves to have a less favourable PSA response to initial hormone treatment. This trial will provide evidence to support whether or not we can extend survival for this group of men with higher-risk disease by introducing chemotherapy earlier alongside hormones. The trial will also establish the impact of side effects from this approach, the potential role of biomarkers for who should receive chemotherapy and cost effectiveness.

Where is the study run from?
Southampton Clinical Trial Unit (UK)

When is the study starting and how long is it expected to run for?
January 2026 to May 2031

Who is funding the study?
Prostate Cancer UK

Who is the main contact?
INTNSIFY@soton.ac.uk

Contact information

Type(s)
Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1010677

Protocol serial number
RHM CAN1899

Study information

Scientific Title
A Phase III open-label randomised trial of androgen deprivation therapy plus androgen receptor pathway inhibition, with or without docetaxel intensification, in metastatic prostate cancer with a PSA ≥0.2 ng/ml at 6 months (INTENSIFY)

Acronym
INTENSIFY

Study objectives
Primary objectives:
1. To compare the effect of treatment intensification with the addition of docetaxel to ADT + ARPI versus continuing ADT + ARPI alone on overall survival
2. To compare the effect of treatment intensification with the addition of docetaxel to ADT + ARPI versus continuing ADT + ARPI alone on overall survival in Decipher Prostate classifier High cancers

Secondary objectives:
To determine the impact of treatment intensification with docetaxel, compared to standard therapy, on:
1. Overall survival in cancers with respect to a PTEN Inactive transcriptome classifier status
2. Overall survival in cancers with a combined Decipher High and PTEN Inactive transcriptome classifier status
3. Overall survival from the start of ADT
4. PSA Progression Free Survival (PFS)
5. Clinical Progression Free Survival (cPFS)
6. Adverse event profiles
7. Health related quality of life
8. Cost-effectiveness

Ethics approval required
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Ethics approval(s)

approved 08/01/2026, West Midlands - Coventry & Warwickshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048255; coventryandwarwick.rec@hra.nhs.uk), ref: 25/WM/0250

Study design
Interventional non randomized

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Metastatic prostate cancer

Interventions
Docetaxel 75mg/m2 IV infusion every 21 days for 6 cycles

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Docetaxel

Primary outcome(s)
Overall survival (OS) defined as the time (in days) from date of randomisation until date of death from any cause:
1. In all patients
2. In a subgroup with Decipher Prostate classifier High cancers

Key secondary outcome(s))
1. PSA PFS defined as the time (in days) from date of randomisation until the earliest date of PSA progression defined in accordance with PCWG3 (a ≥25% increase in PSA and an absolute increase of ≥2 ng/ml, from the PSA nadir and confirmed by a second value ≥3 weeks later) or death from any cause
2. cPFS (clinical PFS) defined as the time from randomisation to date of radiographic progression, PSA
progression, initiation of new prostate cancer treatment or death, whichever occurs first.

Completion date
31/05/2031

Eligibility

Key inclusion criteria

1. Diagnosis of metastatic prostate cancer
2. Histological confirmation of prostate adenocarcinoma with an archival prostate cancer tumour sample available and transferred for central translational analysis prior to randomisation. Patients will be viewed as eligible if a suitable sample is received centrally and analysed. If a Decipher Prostate score or PTEN Inactivity Score cannot be determined for technical reasons, the patient may still be entered and randomised into the trial.
3. Have an initial PSA level, prior to commencing ADT (including any bicalutamide or other AR antagonist run in if used for tumour 'flare' prophylaxis), of ≥2 ng/ml
4. PSA never <0.2 ng/ml since starting hormonal therapy, including a screening PSA level taken within 28 days of randomisation (if more than one PSA level is taken during the 28 days before randomisation, then all must meet this criteria point)
5. Within 5 to 8 months from the first dose of ADT given for mHSPC (or the date of surgical castration) to the date of randomisation. This timing requirement does not indicate from first dose of bicalutamide or other agent for tumour 'flare' cover. Any conventional approach to ADT is acceptable including LHRH antagonists, LHRH agonists, oestradiol patches and surgical castration. If a patient has received prior adjuvant ADT, or other hormonal therapy, they remain eligible if a minimum of 12 months had elapsed between completing adjuvant hormonal therapy and then commencing ADT for mHSPC if there has been documented PSA progression and testosterone recovery (a level above the lower level of normal for the treating institution) in between
6. A minimum of 12 weeks from the commencement of ARPI to the date of randomisation. Abiraterone acetate, enzalutamide, and darolutamide are all acceptable forms of ARPI. Patients may have had ARPI pauses, or switched from one ARPI to another, if this was for reasons of tolerability, toxicity management or to permit trial eligibility (i.e. switching from apalutamide to an alternative), according to local institutional practice, and with the intention of continuing ARPI treatment whilst still in the hormone sensitive setting.
7. Serum testosterone ≤1.7 nmol/L
8. ECOG performance status 0 to 2
9. Adequate clinical, haematological and biochemical parameters to receive docetaxel chemotherapy if allocated, and all relevant supportive medications, and ongoing ADT + ARPI, according to local institutional guidelines and investigator judgement. This must include (within 4 weeks of randomisation):
9.1. Neutrophil count ≥1.5 x 10e9/L
9.2. Platelet count ≥100 x 10e9/L
9.3. Haemoglobin ≥90 g/dL
9.4. Total bilirubin ≤upper limit of normal (ULN), unless the patient has Gilbert's syndrome
9.5. Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) ≤1.5 x ULN.
Patients may have either or both undertaken according to local institutional practice (if both are done during screening then both should satisfy this criterion point)
10. Age ≥18 years
11. Life expectancy anticipated ≥3 months
12. Able to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. Prostate cancer progression to castration resistance as defined and determined by the treating institutional clinical, biochemical (PSA) and/or radiological standards for assessment
2. Active malignancy other than prostate cancer, non-melanomatous skin cancer or non-muscle invasive bladder cancer. A prior cancer diagnosis, where active treatment was discontinued 2 years, or more, prior to randomisation is permitted
3. Previous or current chemotherapy, therapeutic radionuclide, PARP inhibitor or AKT inhibitor treatment for prostate cancer
4. Hypersensitivity to docetaxel or excipients
5. Any serious or unstable medical illness or condition that, in the view of the investigator, could impair the safety of the participant and/or interfere with their compliance with the study procedures, their ongoing use of ADT + ARPI or the use of docetaxel chemotherapy
6. Patients with a partner of child-bearing potential who are not using a highly effective method of contraception, who are unwilling to use condoms during and for 4 months after the last dose of docetaxel

Date of first enrolment
31/03/2026

Date of final enrolment
31/03/2029

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type

Funder Name
Prostate Cancer UK

Alternative Name(s)
Prostate Cancer, Prostate Action, ProstateUK, prostatecanceruk

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date