ISRCTN52361806 https://doi.org/10.1186/ISRCTN52361806

BiopSave: validation of a novel blood test for the diagnosis of prostate cancer

Submission date	Recruitment status	[_] Prospectively registered
07/09/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2021	Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-to-see-if-a-new-blood-test-can-diagnose-prostate-cancer

Contact information

Type(s)
Scientific

Contact name
Mr David Miller

Contact details
Biosignatures Limited
The Biosphere
Draymans Way
Newcastle Helix
Newcastle-upon-Tyne
United Kingdom
NE4 5BX
+44 (0)191 6453645
dave.miller@biosignatures.com

Additional identifiers

Protocol serial number
PR-CT-001 2012/July (02)

Study information

Scientific Title

BiopSave: a blinded, prospective, non-randomised observational controlled study to validate a novel proteomic blood test for the diagnosis of prostate cancer

Acronym
BiopSave

Study objectives
It is hypothesised that a panel of candidate biomarkers, identified during an earlier pilot study as being present in the blood of prostate cancer patients, can be measured using the Biosignatures proteomics platform and successfully used to predict the likelihood of a patient having prostate cancer diagnosed by prostate biopsy. Diagnostic predictions will be made blinded to biopsy result and the accuracy of these predictions compared to actual biopsy results at designated analysis milestones by an independent data monitoring committee. The null hypothesis is that the candidate biomarkers identified during the pilot study had a coincidental association with the patients known to have prostate cancer in that cohort and therefore have no ability to make diagnostic predictions regarding the likelihood of prostate cancer being detected by prostate biopsy in newly recruited patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford C, 19/07/2012, ref: 12/SC/0432

Study design
Blinded prospective non-randomised controlled observational study, with an anticipated duration of 54 months

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Prostate cancer in-vitro diagnostic assay validation

Interventions
Aside from taking of blood samples on one occasion, the study is non-interventional.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
A validation of the performance of the Biosignatures BiopSave product, demonstrating the capability of this proteomic blood test to predict the diagnostic results of prostate biopsies carried out on patients presenting for assessment at urology clinic with the suspicion of having an undiagnosed prostate cancer, particularly those patients in a specific sub-set: PSA

concentration between 2.5 and 20 ng/ml, DRE findings not immediately suspicious of prostate cancer, have not undergone previous prostate biopsy or resection procedures.

Key secondary outcome(s))
1. A validation of the performance of the BiopSave product in patients who have a PSA concentration outside of the primary range of interest and/or who have DRE findings which are suspicious of prostate cancer and/or who have had prostate biopsy or resection procedures carried out in the past.
2. A comparison of the performance of the BiopSave product to a variety of other prostate disease biomarkers recently reported in the literature.
3. An assessment of the capability of the BiopSave product, or related refined versions of the assay to predict the overall prostate disease diagnostic status of study participants one year after initial prostate biopsy.

Completion date
01/07/2018

Eligibility

Key inclusion criteria
1. Are between 40 and 80 years of age
2. Are considered to possibly have an undiagnosed prostate cancer
3. Are considered suitable for prostate biopsy
4. Are able to provide written informed consent agreeing to participation in the study prior to any study-specific procedures being carried out

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
624

Key exclusion criteria
1. Are known to currently have another cancer or have been treated for cancer within the last five years
2. Are not considered suitable for prostate biopsy
3. Are outside of the target age range
4. Are infected with HIV, a viral Hepatitis or another highly-infectious blood-borne disease
5. Are incapable of providing written informed consent agreeing to participation in the study

Date of first enrolment

10/09/2012

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Freeman Hospital
Freeman Road
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Biosignatures Limited (UK)

ROR
https://ror.org/05jhd9y87

Funder(s)

Funder type
Industry

Funder Name
Biosignatures Limited (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from David Miller.

Added 04/05/2021:
The datasets generated during and/or analyzed during the current study are/will be available upon request from Biosignatures Ltd.
What data in particular will be shared? All of the individual participant data collected during the trial, after deidentification.
What other documents will be available? Study protocol, informed consent form, clinical study report.
When will data be available (start and end dates)? Immediately following publication. No end date.
With whom? Investigators whose proposed use of the data has been approved by and independent review committee (IRB/Ethics Committee).
For what types of analyses? To achieve the aims in the approved proposal.
By what mechanism will data be made available? Proposals should be directed to the Newcastle Biobank (https://www.ncl.ac.uk/biobanks/researchers/sample-access/)
Whether participant consent was obtained? Participants gave consent for the use of their blood samples and deidentified data to be used for future research, as a “gift to science”.
Comments on data anonymization. Identifiable data was not accessed outside of the care team. At recruitment participants were assigned a unique alpha-numeric identification code by research nursing staff. All information and blood samples which left the clinical site were only identifiable by this unique code.
Any ethical or legal restrictions? None.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		04/05/2021	07/05/2021	No	No
Participant information sheet	version V2		05/05/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes