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

HEALTH PROFESSIONAL INFORMATION SHEET

USING BLOOD SAMPLES TO DIAGNOSE PROSTATE CANCER

This sheet provides technical information on a clinical research study.
It is designed to inform health care professionals about the techniques used and goals of the study. It also has an overview of what will happen to participants and how data and information will be handled.

This sheet is not designed for participants.
Please refer to the "Participant Information Sheet". This sheet is designed to provide additional information for GPs whose patients have decided to participate in the study.

If you require further information please use the contact details at the end of this sheet.

Part 1 covers general details and Part 2 has more specific information.

PART 1

What is the purpose of the study?

This study is a research project, which is intended to validate the performance of a new blood test, 'BiopSave', which has been developed by a Newcastle-based company, Biosignatures Ltd.
A substantial number of prostate biopsy procedures are carried out each year on patients who are suspected of having prostate cancer.

However, the majority of these procedures have negative findings, meaning that in theory, they were carried out unnecessarily.
The BiopSave assay is intended to be used as a screening tool prior to prostate biopsy to distinguish patients who appear to have a high likelihood of having prostate cancer (and therefore certainly require a biopsy) from those who have a low likelihood of having prostate cancer and therefore can be investigated in a less invasive manner.
The study will run for 24 months and will routinely process between 30 and 50 participants per month.

The BiopSave assay is a 'clinical laboratory test' and not a point of care kit. The approach used is termed a 'multiplex assay' and consists of measuring many thousands of proteins in a sample simultaneously, using combinations of these measures to create new diagnostics and prognostics.

How are the participants chosen?
We need participants with a variety of conditions and also people who are healthy. The 'population' the study is interested in is all patients that have been referred to a urology clinic for further investigation, who go on to have a prostate biopsy test carried out. Being chosen for this study does not mean a participant has a specific urological condition.

What happens to the participants that take part?
There will be no changes to treatment. We will collect some additional information and a blood sample from all participants.

Whilst at the clinic, all the people taking part in the research project will be asked to provide a small blood sample and asked some questions about any medications they are on and some aspects of their medical history. Wherever possible the blood sample will be taken at the same time as any sample taken as part of the standard clinical assessment and will require no additional procedures.

The medical team will continue to access participant medical records so they can perform follow-up checks and monitor any changes to the patient's diagnosis. This is necessary, as it is known that prostate biopsies have a false negative rate of around 20 to 25%. It will be very interesting to look back over this data and see if the results obtained from the BiopSave blood test could be used as an early warning for a prostate cancer which is subsequently diagnosed after a patient's first biopsy is found to be negative for cancer.

This is an observational study. We gather information from lots of people and conditions and from this see if we can test for these in the provided samples.

What is the study trying to test?
Some conditions, for example diabetes, can already be diagnosed from blood. This study is trying to create more tests for other diseases, such as cancer, especially where these blood tests can replace or reduce the number of invasive tests such as biopsies that are carried out.

What are the possible disadvantages and risks of taking part?
There should be no disadvantages or risks to taking part. Treatment will be unaffected by taking part or not. The blood sample is a small amount and in the worst case participants may experience some slight bruising from where the sample was taken. Wherever possible the sample will be taken at the same time as they provide samples during clinical assessment and so should involve no additional risks or discomfort.

What are the possible benefits of taking part?
The trial will not help the participants personally but the information we get from this trial could help improve the diagnosis and treatment of prostate conditions in the future.

PART 2

What will happen if a participant does not want to continue with the study?
Participants can withdraw from the study at anytime and without giving a reason. If they withdraw from the study, we will destroy all identifiable samples, but we will need to use the data collected up to the withdrawal.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions:
Research Nurse: Wendy Robson, 0191 2137322
Principal Investigator: Mr Naeem Soomro, Clinical Consultant Urologist, 0191 2336161

There is a small chance that results from this study will suggest participants have a condition of which they are unaware. This will come about by a participant being associated with a group with a diagnosed condition after the analysis has been done. This will not be a diagnosis but it may suggest further standard clinical tests should be run just to be sure. In such circumstances, participants will be referred to the appropriate specialist in consultation with their general practitioner, unless participants have said they do not wish to do so. Such detection has the benefit of starting treatment early but in a small number of cases may have implications for future employment and insurance.

We realise this is a difficult issue as a false diagnosis could cause a great deal of undue stress on the participant. The medical team will discuss such cases in detail and use their experience to decide the course of action that is in the best interests of the participant. If the team decides that further action is warranted, the participant's GP will be consulted so a consensus decision can be reached regarding the best interests of their patient.

Will participants taking part in this study be kept confidential?
There are very strict rules about collecting medical research information under the 1998 Data Protection Act. We must comply with this act and keep participant information safe. Any Information that leaves the hospital will have names and addresses removed.

The information accessed for the research will be about diagnosis and long term state of health.

Participant's GPs will not normally be notified that their patients are taking part in this study, but a member of the medical team will do so if requested by the participant.

All information collected during the course of the research will be kept strictly confidential, and any information which leaves the hospital will be anonymised so that participants cannot be identified.

What will happen to the samples?
The blood samples will be sent anonymously to a laboratory and processed. The result of the processing is to measure relative quantities of many thousands of constituents of blood. Reports have suggested that in excess of 10,000 distinct proteins can be measured in blood plasma. Many of these proteins have been predicted from analysis of the genome but have yet to be assigned a function. There are many measurement techniques but at present it is possible to measure a few thousand proteins simultaneously from a single sample and single processing technique. Many of the proteins (e.g. PSA) are already clinically useful. The following URL gives an example of such a multiple measurement array with clinically relevant analytes http://www.whatman.com/SerumBiomarkerChip.aspx .

Further research has shown that some of the markers (e.g. PSA) can be made more reliable by not just taking a single measure and comparing it to an absolute concentration. This study will be extending this by taking the thousands of relative measures from a single sample and combining them in a way that is diagnostic of prostate disease.

We will be taking around 10 mL of blood (a single vacutainer) which produces about 8.5 mL of plasma to analyse, in addition to the serum sample taken from patients which is required for routine PSA measurement.

These measurements will be combined with information about the participant's medical history and lifestyle to see if they can be used to predict the diagnostic results obtained from a prostate biopsy, carried out shortly after the patient's blood is sampled. Only the medical team on the clinical site will have access to records which disclose information about diagnoses which are reached.

We would like to consider the 'samples as a gift to science'. By this we mean that, if participants are happy for us to do so, remaining sample not used in this study could be used in ethically approved follow on research. The same strict controls on confidentiality will be in place.

An example of this may be trying to find new treatments for cancer. Participants can opt out of this and have their samples only used in this study. If they consent to this further use, the remaining samples will be transferred to a government licensed tissue bank where they can only be used in research that has been reviewed and received a favourable ethical opinion.

No genetic tests will be carried out as part of this study.

What will happen to the results of the research study?

- The results will be published in scientific journal.
- If diagnostic signatures of disease are validated they will be commercialised and put into practice as soon as is practical
- At no time will participants be identified in person.

An overview of results of the research will also be presented on the sponsor's website http://www.biosignatures.com/BiopSave to allow participants to follow overall progress.

Who is organizing and funding the research?
The driving force behind this research study is a local company:

Biosignatures Ltd. is a small company based in Newcastle. If successful this study would be recognised internationally and showcase the scientific abilities of the region.

This study has been designed and conceived by Biosignatures who are also providing the funding. Although it is hoped that the research will go on to benefit patients within the NHS the clinical staff have been contracted to participate in this study and did not instigate it.

The sponsor is paying the hospital to employ a full time research nurse and to have some time from the experts in the clinic. The contract is for a fixed time and there is no per patient payment or incentives for any of the clinical staff. No Biosignatures staff work in the clinic and everyone that patients meet in the clinical setting will be employed, trained and managed by the hospital.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect patient safety, rights, wellbeing and dignity.

This study has been reviewed and given favourable opinion by the Oxford C Research Ethics Proportionate Review Sub-Committee.

This study has also been reviewed and approved by The Newcastle Upon Tyne Hospitals NHS Foundation Trust.

Thank you for reading this information leaflet.
If you have problems or questions please do not hesitate to get in touch.

Please use one of the following contact numbers:

Freeman Urology clinical team:

Research Nurse: Wendy Robson, **tel:** 0191 2137322
Principal Investigator: Mr Naeeem Soomro,
email: naeem.soomro@nuth.nhs.uk **tel:** 01912336161
Address: Urology Renal Medicine, Freeman Hospital, NE7 7DN

Biosignatures Ltd.,

Clinical Operations Manager: Dave Miller
email: info@biosignatures.com
web: http://www.biosignatures.com
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Address: Dean Court, 22 Dean Street, Newcastle upon Tyne. NE1 1PG

Additional and updated information is available here:
http://www.biosignatures.com/BiopSave