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Use of [-2]proPSA for the detection of prostate cancer in patients who are candidate for prostatic biopsy

Submission date
10/11/2011

Recruitment status
No longer recruiting

Registration date
19/12/2011

Overall study status
Completed

Last Edited
03/11/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to investigate how well a new biomarker (a substance used as an indicator of the presence of prostate cancer) works to improve the detection of prostate cancer and reduce the number of negative prostate biopsies (where tissue is unnecessarily removed as it is not cancerous).

Who can participate?
Men from the participating institution scheduled for a prostate biopsy (removal of cancerous tissue), based on clinician decision.

What does the study involve?
One single blood sample was taken from those participating (which is already part of the standard care, for patients schedule for prostate biopsy). All patients will receive the appropriate treatment according to their condition and the study will have no influence of any kind on the choice of treatment offered to the patients.

What are the possible benefits and risks of participating?
Development of the new biomarker could improve detection of prostate cancer and reduce the number of negative prostate biopsies that are common with existing tests. This new biomarker can improve patient care by reducing the number of invasive and costly procedures. There are no known risks associated with this study.

Where is the study run from?
San Raffaele Hospital-Turro , Milan, Italy (Lead center).
Other centers: Hopital Henri Mondor, Paris, France; Fundacio Puigvert, Barcelona, Spain; University Hamburg-Eppendorf, Hamburg, Germany; Lister Hospital, Stevenage, UK

When is study starting and how long is it expected to run for?
Recruitment started in December 2011 and ended in March 2012. The study ran for 9 months.

Who is funding the study?
Beckman Coulter, Switzerland

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2PROPSA

Study information

Scientific Title
Evaluation of the of the sensitivity, specificity and diagnostic accuracy of the [-2]proPSA biomarker and its derivatives for the detection of prostate cancer and determination of the relationship with prostate cancer characteristics at biopsy

Study objectives
The two most commonly used tests for prostate cancer detection are digital rectal examination and serum prostate-specific antigen (PSA) level. In the last two decades, PSA has considerably improved our ability to detect prostate cancer (PCa). However, this marker has some limitations in sensitivity and specificity for prostate cancer detection leading to false negative and false positive results. Thus, in the recent years, several promising biomarkers have been studied in

order to improve PSA specificity in the early detection of PCa. Preliminary reports have shown that some PSA precursors such as [-2]proPSA may be more specific than total PSA or free PSA in predicting the presence of PCa especially in the PSA range between 2 and 10 ng/mL. The goal of this trial is to test the ability of [-2]proPSA and its derivatives in discriminating between patients with or without PCa within a prospectively collected, multicentric, European, large and contemporary cohort of candidates for a prostate biopsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, San Rafaele Hospital Milan, Italy, 08/04/2010, ref: 2PROPSA

Study design
Non-randomized observational multicenter trial

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
For each patients included, as part of the standard care at each institution, blood will be drawn and serum (blood centrifuged and serum collected) will be prepared within 3 hours of the blood draw. The serum samples will be coded so that no patients name or details will be recorded. The serum samples will be then frozen at -20°C or -70°C. The samples will be then sent to Hospital San Rafaele in Milan for the determination of the PSA, fPSA and [-2]proPSA serum concentrations and calculation of the prostate health index (phi). The patients clinical information including diagnostic will be collected and coded at each institution and sent to the data manager at Hospital San Rafaele. The statistical analysis will be then performed at Hospital San Rafaele in Milan on the complete data set including laboratory information (PSA, fPSA, [-2] proPSA, phi) and clinical information. The performance of the new diagnostic test will be assessed in comparison with currently used test such as tPSA or %fPSA using ROC curve analysis, univariate and multivariante logistic regression and determination of gain in clinical specificity at a given sensitivity. Each patients included in the trail will be followed at each intitution for a period of 6 months following the initial blod draw.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Evaluate the specificity, sensitivity and diagnostic accuracy of -2proPSA and its derivatives (index text) in determining the presence of PCa at prostate biopsy and to compare them with those of total and free PSA (referenced text). Thus, we will quantify the number of prostate biopsies that can be spared using -2proPSA in the prostate biopsy decision path.

Secondary outcome measures
1. Determine a -2proPSA (and its derivatives) cut-off value to be used in clinical practice
2. Determine the relationship between -2proPSA (and its derivatives) and PCa characteristics at biopsy (e.g. Gleason grade, % of cores involved, % of involvement of a single core)

Overall study start date
01/05/2011

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Male patients older than 45 years old
2. Negative/positive digital rectal examination
3. Patients subjected to previous prostate biopsy will be included and analyzed in a nested case control study
4. Patients treated with drugs that may alter serum PSA levels (Finasteride and Dutasteride) will be included and analysed later in a nested case control study

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
1250

Key exclusion criteria
1. Patients with bacterial acute prostatitis and with a positive sperm culture in the last three months prior to biopsy
2. Patients subjected to previous endoscopic surgery of the prostate (TransUrethral Resection of the Prostate [TURP] or Holmium-laser Enucleomorcellation of the Prostate [HoLEP]

Date of first enrolment
01/12/2011

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
France

Germany

Italy

Spain

United Kingdom

Study participating centre
San Raffaele Turro Hospital
Milan
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Sponsor information

Organisation
Beckman Coulter Eurocenter (Switzerland)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Beckman Coulter Eurocenter S.A. (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2014		Yes	No