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4-Kallicreins score study as a predictor of tumor reclassification in a program of active surveillance of prostate cancer.

Submission date 01/02/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/04/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 22/04/2016	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
In cases of low risk prostate cancer (that is, cancer that is local and has not spread to other parts of the body), active surveillance rather than treatment may be appropriate. This is because prostate cancer is often slow growing and may not cause any issues as a result. Kallikrens are a group of proteins that can be used to predict the risk of prostate cancer. The aim of this study to see if they can be used as a predictor of how much the cancer has progressed – that is, can a test called 4Kallicreins help to reclassify prostate cancer tumors.

Who can participate?
Men with a diagnosis of low risk prostate cancer tan are under 80 years of age and are expected to live for at least 10 years.

What does the study involve?
Participants are asked to attend three visits during the study period. The first visit happens between days 0-15, the second visit at day 180 and the third visit at day 195 of the study period. During these visits, their details are added to a patient database and they are sked to give blood and biopsy samples for analysis.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Urology Service, Valencian Institute of Oncology (Spain)

When is the study starting and how long is it expected to run for?
December 2014 to December 2015

Who is funding the study?
Spain Urology Association (AEU)

Who is the main contact?
Dr Sara Martinez Breijo

Study website
http://piem.aeu.es/proyectos/VACP/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PIEMAEU/ 2014/001

Study information

Scientific Title
4Kscore as a predictor of tumor reclassification.

Study objectives
The test of 4Kallicreins can be used to predict tumor biopsy reclassification confirmation within a program of active surveillance of low risk prostate cancer (CaP).

Definition of tumor reclassification;
1. Screening biopsy-confirmed, reviewed by Central uropatologhist, Gleason Prostate cancer ≥7 and/or
2. Detection in biopsy confirmation of a larger number of affected cylinder (> 2 in transrectal biopsy confirmation (18 cylinders), or> 2 and more than 2 affected areas in transperineal biopsy confirmation (up to 24-32 cylinders) guided by brachytherapy, or> 5 mm, or 50% involvement of 1 cylinder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Galicia clinical research ethics committee (CEIC), 29/07/2014, ref: CEIC 14/242

Study design
Prospective blind non-randomised

Primary study design
Observational

Secondary study design
Prospective blind non-randomised

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Spain male residents diagnosed with low risk CaP (NCCN)

Interventions
It is a protocol for active surveillance during which the test 4Kscore is assessed in a population with low-risk PCa to know its behavior as a predictor of tumor reclassification biopsy confirmation, and even build a specific predictive model in this substrate PCa patients with known sample size needed.

STUDY TIMETABLE
1. First visit (Days 0-15):
1.1. Voluntary report and Informed Consent
1.2. Clinic history
1.3. Inclusion and exclusion criteria review

1.4. Patient inclusion in the database of the PIEM-AEU/2014/001
1.5. Slides from diagnostic biopsy are sent to central lab
1.6. Definitely inclusion confirmation by IVO anatomic pathology
2. Second visit (Day 180):
Blood collection, delivery and implementation of 4Kscore test in Clínic Hospital
2.1.Including sample 4KScore code for the patient in the PIEM database
2.2. Perform biopsy confirmation (after 4Kscore test)
3. Third visit (Day 195):
3.1. Reception biopsy confirmation report
3.2. Implementation biopsy confirmation results in the database of PIEM-AEU/2014/001
3.3. Remission of biopsy confirmation slides to IVO

Intervention Type
Procedure/Surgery

Primary outcome measure
To determine the value of the 4Kscore test as a predictor of tumor reclassification in an active surveillance program in Prostate Cancer (PCa).

A sample of whole blood will be collected, six months after diagnostic biopsy, always before digital rectal examination if it is repeated at 6 months and proceed to dispatch in accordance with instructions OPKO Health Spain SL. The result will be stored in a database to analyze the results and sent to the principal investigators after the study. The research partners will include sample code for each patient in the database of PIEM, thus the traceability of the sample is guaranteed and will enable leading researchers characterize their code samples. No type of therapeutic action is permitted until after the biopsy confirmation, since the analysis of the results will be centralized and blinded manner, after confirmation biopsies done.

Secondary outcome measures
1. Free survival of active treatment: means the time elapsed between the entry into active surveillance with the initial biopsy and the adoption of a active treatment such as prostatectomy, brachytherapy, Radiotherapy Treatment or Focal Ablation Techniques
2. Progression-free survival: defined as the time to the pathological tumor progression during follow-up, defining this with the same conditions but detected in tumor reclassification follow-up biopsies. It is also understood as progression if the researcher associated defines the presence of local or regional progression by physical or radiological examinations

Overall study start date
01/12/2014

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. PSA ≤ 10 ng / mL; if prostate volume> 60 cc in transrectal, ultrasound included with PSA>10 ng / ml if PSAD <0.20
2. Local Stadium DRE; cT1c -cT2a
3. Diagnosis of transrectal ultrasound guided biopsy minimum 10 cylinders
4. Adenocarcinoma Prostate Gleason ≤ 6 (3 + 3) with local and central pathology review

5. Maximum number of cylinders = 2 and none of them more than 5mm tumor or more than 50% of
assignment
6. <80 years and greater expectancy to 10 years life (Charlson score)
7. Patients able to understand VA and sign the informed consent
8. Possibility for the Hospital Project and associated patient acceptance at inclusion to performance the test of 4Kscore followed by a biopsy confirmation at 6 months diagnostic. This transrectal ultrasound-guided biopsy may be making 18 cylinders or ultrasound-guided transperineal brachytherapy making from 24 to 32 cylinders according with prostate volume. Both possibilities allow extra biopies to confirm suspected areas by ultrasound or RMNmp 1.5T (which is optional)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
300

Key exclusion criteria
1. Patient not be able to accept repeat biopsies
2. Patient who does not want to sign the Informed Consent
3. Hospital where the possibility of a biopsy confirmation at 6 months is not guaranteed under the terms of the inclusion criteria
4. If the central pathology review of diagnostic biopsy is estimated not met
inclusion criteria marking the protocol
5. Patients with a history of ASAP (atypical small acinar proliferation or atypical microglándulas)
6. Patients with treatment with inhibitors of 5-alpha-reductase as dutasteride (Avodart®) and finasteride (Proscar®) during the previous six months
7. Patients who have undergone during the 6 months prior to any treatment symptomatic benign prostate hyperplasia, or any invasive urological procedure. It can be associated with an increase of PSA prior to phlebotomy. These therapies include, but they are not limited to, prostate biopsy, thermotherapy, microwave therapy, laser, urethral resection of the prostate, urethral catheterization and the lower genitourinary tract endoscopy

Date of first enrolment
01/12/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Spain

Study participating centre
Urology Service, Valencian Institute of Oncology (Servicio Urología, Instituto Valenciano de Oncología)
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Study participating centre
Urology Service, University Hospital Miguel Servet in Zaragoza (Servicio Urología, Hospital Universitario Miguel Servet de Zaragoza)
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Sponsor type
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Sponsor type
Hospital/treatment centre

Organisation
Fundación Instituto Valenciano de Oncología

Sponsor details

Sponsor type
Not defined

Website
http://www.ivo.es/

ROR
https://ror.org/01fh9k283

Funder(s)

Funder type
Not defined

Funder Name
Spain Urology Association (AEU)

Results and Publications

Publication and dissemination plan

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration