ISRCTN31825442 https://doi.org/10.1186/ISRCTN31825442

Prostate Cancer Antigen 3 (PCA3) and functional Magnetic Resonance Imaging (MRI) in prostate cancer diagnosis

Submission date 18/02/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/03/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/03/2010	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sisto Perdona

Contact details
UOC Urologia
INT Fondazione "G. Pascale"
Via M. Semmola
Napoli
Italy
80100

Additional identifiers

Protocol serial number
INTURO0110

Study information

Scientific Title
Prostate Cancer Antigen 3 (PCA3) and functional Magnetic Resonance Imaging (MRI) in prostate cancer diagnosis: A prospective multicentre study

Study objectives
By combining PCA3 testing and functional MRI imaging it is possible to improve sensitivity and specificity of current diagnostic tools in the management of patients at risk for prostate cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of the National Cancer Institute (Istituto Nazionale Tumori [INT]) - G Pascale Foundation (Fondazione G. Pascale) approved on the 29th of September 2009 (ref: DSC /2287)

Study design
Prospective multicentre observational study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
Visit 0 (baseline): screening for inclusion/exclusion criteria; informed consent; demographic data collection
Visit 1 (within the 1st week): functional MRI
Visit 2 (after 1 week): urine sample collection for PCA 3 assessment (Progensa PCA3™, Gen-probe Inc.); Prostate biopsy
Visit 3 (at 1 month): registration of complications; discussion of biopsy outcome (if negative, follow up; if positive, clinical staging and treatment)
Visit 4 (at 4 months): re-biopsy if indicated

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. To estimate the diagnostic accuracy in terms of sensibility, sensitivity and predictive values of PCA3
2. To assess the diagnostic accuracy of morphologic and spectroscopic MRI in relation to PCA3 and biopsy outcomes

Key secondary outcome(s))

1. To determine the best PCA3 cut-off score in terms of sensitivity and specificity
2. To correlate PCA3 to other known parameters (PSA, Gleason score, tumour stage)
3. To estimate the advantages of a new diagnostic algorithm in comparison with current standards on the basis of clinical and socio-economical parameters

Completion date
30/10/2011

Eligibility

Key inclusion criteria
1. Age >45 yrs
2. Able to comply with the protocol procedures
3. Able to understand and give consent to the protocol procedures
4. Indication for prostate biopsy or re-biopsy based on clinical parameters and prostate-specific antigen (PSA) values

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
Male

Key exclusion criteria
1. PSA > 10 ng/ml
2. Therapy with finasteride or dutasteride in the previous 6 months
3. Unable to follow the protocol procedures and to give informed consent
4. Recent history of drug or alcohol abuse

Date of first enrolment
01/11/2009

Date of final enrolment
30/10/2011

Locations

Countries of recruitment
Italy

Study participating centre

UOC Urologia
Napoli
Italy
80100

Sponsor information

Organisation
National Cancer Institute (Istituto Nazionale Tumori [INT]) - G Pascale Foundation (Fondazione G. Pascale) (Italy)

ROR
https://ror.org/05dwj7825

Funder(s)

Funder type
Research organisation

Funder Name
National Cancer Institute (Istituto Nazionale Tumori [INT]) - G Pascale Foundation (Fondazione G. Pascale) (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration