

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/03/2010	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

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™, Genprobe 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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2009

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

Age group

Other

Sex

Male

Target number of participants

1000

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)

Sponsor details

Via M Semmola

Napoli

Italy

80100

Sponsor type

Research organisation

Website

<http://www.fondazionepascale.it>

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

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