

Comparison of 12-core versus 18-core biopsy in transrectal ultrasound-guided prostate biopsy for prostate cancer diagnosis

Submission date 26/08/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/09/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/09/2010	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

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Comparison of 12-core versus 18-core biopsy in transrectal ultrasound-guided prostate biopsy for prostate cancer diagnosis: a randomised controlled trial

Study objectives

Increasing the number of cores from 12 to 18 during transrectal ultrasound-guided prostate biopsy will improve cancer detection rate of this diagnostic procedure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Institutional Committee of Biomedical Investigation in Humans of the Salvador Zubiran National Institute of Nutrition (Instituto Nacional de la Nutricion Salvador Zubiran) approved on the 18th of December 2008 (ref: 1940)

Study design

Single centre prospective randomised controlled trial

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Patients undergoing transrectal ultrasound-guided prostate biopsy will be randomised to:

1. Study group: 18-core biopsy
2. Control group: 12-core biopsy

All procedures performed under mild intravenous sedation, outpatient basis.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Prostate cancer detection rate

Key secondary outcome(s)

1. Detection of 'clinically insignificant' prostate cancer
2. Comparison of pain through visual analog scale (VAS) between groups at baseline and 7 days after the procedure with a questionnaire
3. Complication rate evaluation in both groups at baseline and 7 days after the procedure with a questionnaire

Completion date

31/01/2010

Eligibility

Key inclusion criteria

1. Male patients
2. Age 45 to 75 years old
3. Prostate-specific antigen ranging from 4 to 20 ng/ml and/or suspicious digital rectal examination, requiring transrectal ultrasound-guided prostate biopsy for the first time

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

1. Previous prostate cancer diagnosis
2. Previous prostate surgery
3. Previous prostate biopsy
4. Prostate-specific antigen above 20 ng/ml
5. Previous intake of 5-alfa reductase inhibitors (finasteride or dutasteride)
6. Previous intake or use of hormonal therapy

Date of first enrolment

01/01/2009

Date of final enrolment

31/01/2010

Locations

Countries of recruitment

Mexico

Study participating centre

Vasco de Quiroga 15

Mexico City

Mexico

14000

Sponsor information

Organisation

Salvador Zubiran National Institute of Nutrition (Instituto Nacional de la Nutricion Salvador Zubiran) (Mexico)

ROR

<https://ror.org/00xgvev73>

Funder(s)

Funder type

Research organisation

Funder Name

Salvador Zubiran National Institute of Nutrition (Instituto Nacional de la Nutricion Salvador Zubiran) (Mexico)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration