ISRCTN65812524 https://doi.org/10.1186/ISRCTN65812524

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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/09/2010	**Overall study status** Completed	
Last Edited 06/09/2010	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Francisco Rodriguez-Covarrubias

Contact details
Vasco de Quiroga 15
Col. Seccion XVI
Tlalpan
Mexico City
Mexico
14000
frodriguez.covarrubias@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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 measure
Prostate cancer detection rate

Secondary outcome measures
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

Overall study start date
01/01/2009

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

Age group
Adult

Sex
Male

Target number of participants
150 participants, randomly assigned to study group (75 patients) or control group (75 patients)

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)

Sponsor details
Vasco de Quiroga 15
Col. Seccion XVI
Tlalpan
Mexico City
Mexico
14000
francisco.rodriguezc@quetzal.innsz.mx

Sponsor type
Research organisation

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

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