ISRCTN60263108 https://doi.org/10.1186/ISRCTN60263108

Biopsy diagnosis of prostate cancer in patients with suspected prostate cancer undergoing their first biopsy: comparison of target biopsy alone vs target biopsy in addition to standard biopsy

Submission date
31/01/2022

Recruitment status
No longer recruiting

Registration date
09/03/2022

Overall study status
Completed

Last Edited
11/01/2023

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recently, thanks to the introduction of multiparametric prostate magnetic resonance imaging (mp-MRI scans), it is possible to perform targeted prostate biopsies (tissue samples) on patients with suspected prostate cancer with the intent to reduce the number of samples per single biopsy, increasing the diagnostic accuracy. While performing a targeted biopsy alone in patients with positive mp-MRI and a negative previous random biopsy is a well-validated practice, this method is still under scrutiny in the setting of patients undergoing their first biopsy. The aim of this study is to compare the prostate cancer detection rate of a diagnostic pathway based on target biopsy samples versus a diagnostic pathway based on target biopsy samples plus random samples.

Who can participate?
Patients aged under 75 years with an indication for a prostate biopsy for suspected prostate cancer and positive mp-MRI

What does the study involve?
Participants are randomly allocated to either a diagnostic pathway based on target biopsy samples or a diagnostic pathway based on target biopsy samples plus random samples. The detection rate of clinically significant prostate cancers is compared between the two pathways.

What are the possible benefits and risks of participating?
The benefit of this study is a reduction in the number of biopsy samples, with a likely reduction in the duration and side effects of the procedures. About 5-7% of clinically significant prostate cancers are diagnosed only at standard biopsy with negative target samples. To avoid the risk of missed diagnosis, patients enrolled in the study who are biopsy negative undergo close follow-up.

Where is the study run from?
San Luigi Gonzaga University Hospital (Italy)

When is the study starting and how long is it expected to run for?
January 2019 to October 2021

Who is funding the study?
San Luigi Gonzaga University Hospital (Italy)

Who is the main contact?
Prof. Francesco Porpiglia
porpiglia@libero.it

Contact information

Type(s)
Principal investigator

Contact name
Prof Francesco Porpiglia

ORCID ID
https://orcid.org/0000-0002-0752-4857

Contact details
San Luigi Gonzaga University Hospital
Regione Gonzole 10
Orbassano (Turin)
Italy
10043
+39 (0)119026485
porpiglia@libero.it

Additional identifiers

Protocol serial number
3524

Study information

Scientific Title
Biopsy diagnosis of prostate cancer in naïve patients. Comparison of target biopsy alone vs. target biopsy in addition to random: a prospective randomized trial

Study objectives
To compare, in naïve patients with suspected prostate cancer and positive multiparametric prostate magnetic resonance imaging (mp-MRI), the detection rate of clinically significant prostate cancer of a diagnostic pathway based on target biopsy samples vs a diagnostic pathway based on target biopsy samples plus random samples.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/03/2019, Ethics Committee San Luigi Gonzaga Hospital (regione gonzole 10, Orbassano (TO), 10043, Italy; +39 (0)11 9026204, +39 (0)11 9026 566; sperimentazioni@sanluigi.piemonte.it), ref: 3524

Primary study design
Interventional

Study design
Single-centre interventional randomized controlled trial

Study type(s)
Diagnostic

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

Interventions
The primary objective of the study is to compare, in naïve patients with positive MRI, the detection rate of clinically significant prostate cancer of a diagnostic pathway based on target biopsy samples vs a diagnostic pathway based on target biopsy samples plus random samples. The patients underwent two-arm randomization via specific "query" to the website https://www.randomization.com. Patients were randomly assigned to undergo fusion biopsy alone (Group A) or fusion biopsy plus standard biopsy (Group B). Transrectal ultrasound was performed using a Hawk Ultrasound scanner 2102 EXL with a biplanar transducer, biopsies were performed using a disposable 18-gauge biopsy gun with a specimen size of 18–22 mm. Fusion biopsy was executed using the BioJet fusion system, for patients enrolled in Group B, in accordance with the protocol by Rodríguez-Covarrubias et al, a standard biopsy was performed obtaining 12 cores via a transrectal approach.

The Gleason score (GS) of the biopsy, number of total and positive cores, total and maximum cancer core length (CCL) and maximum cancer core invasion (CCI) rate were acquired in accordance with the standards of reporting for MRI targeted biopsy studies (START) criteria. Clinical significant Prostate Cancer (csPCa) was defined when START criteria for target biopsy (biopsy GS ≥7 or maximum CCL ≥5 mm) and updated Epstein criteria for Standard Biopsy were met. Prostate specimens from patients who underwent robot-assisted radical prostatectomy (RARP) were chosen as the reference standard. The organ’s processing was executed following the aforementioned technique, subsequently calculating GS and ISUP grade for each lesion found. 30-days biopsy related complications were classified according to the Clavien–Dindo classification. The Detection Rate was set as the ratio between the total cases of PCs/csPCs diagnosed thanks to a particular biopsy (FB, FB + SB or SB) and the total number of patients.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Detection rate (DR) of clinically significant prostate cancer (csPCa) by fusion biopsy alone (Group A) versus fusion biopsy plus standard biopsy (Group B), set as the ratio between the total cases

of csPCs diagnosed and the total number of patients. Evaluated after the histological examination.

Key secondary outcome(s)
1. 30-days biopsy related complications classified according to the Clavien–Dindo classification at 30-days follow up
2. The overall DR of prostate cancer by fusion biopsy alone (Group A) versus fusion biopsy plus standard biopsy (Group B). Evaluated after the histological examination.
3. Whole-mount histopathological findings after RARP compared with biopsy findings in both study groups, evaluated after the histological examination

Completion date
15/10/2021

Eligibility

Key inclusion criteria
1. Age <75 years
2. Negative history of previous prostate biopsies
3. Suspected serum prostate-specific antigen (PSA) values <15 ng/ml
4. Negative rectal examination (DRE)
5. Positive multiparametric magnetic resonance imaging

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
Male

Total final enrolment
384

Key exclusion criteria
Contraindications to prostate biopsy (e.g., inability to discontinue anticoagulant therapy)

Date of first enrolment
11/04/2019

Date of final enrolment
01/10/2021

Locations

Countries of recruitment

Italy

Study participating centre
San Luigi Gonzaga University Hospital
Regione Gonzole 10
Orbassano (Turin)
Italy
10043

Sponsor information

Organisation
Ospedale San Luigi Gonzaga

ROR
https://ror.org/04nzv4p86

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	primary results	10/01/2023	11/01/2023	Yes	No