- **Project title:** **MULTICENTRE PROSPECTIVE OBSERVATIONAL STUDY OF PROSTATE RESCUE WITH HIGH-RATE BRACHYTHERAPY. (PROSCATE).**

- **NCT number:**
  - NCT07860528

- **Protocol code**:
  - PROSCATE.
- **Protocol version dated**:
  - Version dated 22 September 2026
- **Sponsor:**
  - IRAD (Institute for Research in Radiation Oncology), SEOR (Spanish Society of Radiation Oncology).
- **Principal investigator:**
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PROTOCOL SIGNATURE SHEET

Protocol code: PROSCATE.

Protocol version dated: Version 2, 22 September 2026

Sponsor:

IRAD (Institute for Research in Radiation Oncology)
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1. Abstract

- Project title: MULTICENTRE PROSPECTIVE OBSERVATIONAL STUDY ON PROSTATE RESCUE WITH HIGH-RATE BRACHYTHERAPY.
- Protocol code: PROSCATE.
- Sponsor and Principal Investigator: IRAD (Institute for Research in Radiation Oncology), SEOR (Spanish Society of Radiation Oncology).
- Centers where the study is planned to be conducted:
  - Meixoeiro Hospital, Vigo.
  - Onkologickoa. San Sebastián Cancer Institute.
  - Marqués de Valdecilla Hospital, Santander.
  - Cruces Hospital, Bilbao.
  - Ramón y Cajal Hospital, Madrid.
  - La Fe Hospital. Valencia.
  - ICO Barcelona.
  - Navarre University Hospital. Pamplona.
  - Córdoba University Hospital. Córdoba.
  - Benidorm Clinic. Benidorm.
- Study design: Prospective observational.
- Condition under investigation:

We propose a prospective, observational, multicenter study to analyze the treatment of prostate recurrence diagnosed using next-generation techniques (Choline PET / PSMA PET), MRI and a positive biopsy, treated with two fractions of high-dose-rate brachytherapy.

- Primary and secondary objectives:

The objectives of this prospective multicenter study are:

- Primary:

1. Biochemical relapse-free survival, defined as the time to biochemical relapse (nadir plus 2 — Phoenix criterion).

- Secondary:

1. Local relapse-free survival: defined as the time from treatment to local relapse as confirmed by imaging (Choline PET/MRI).
2. Analysis of acute and chronic toxicity.
3. Study of patients' quality of life before and after treatment, to analyze the impact that local re-irradiation may have on a patient's daily life.

- Primary endpoint: Biochemical relapse-free survival and study of toxicity and quality in patients treated with rescue brachytherapy following radical treatment.
- Study population and total number of subjects.

Patients treated with radiotherapy with curative intent as first-line treatment (brachytherapy alone, external beam radiotherapy or external beam radiotherapy plus a brachytherapy boost) who have been diagnosed with a local recurrence using next-generation techniques (Choline PET / PSMA PET) and prior biopsy, who are to undergo rescue brachytherapy as part of standard clinical practice, with a calculated sample size of 63 patients.

2. Background and rationale for the project:

Radical radiotherapy for prostate cancer is the standard of care, alongside radical prostatectomy, in the treatment of localized disease (1). One third of these patients treated with radiotherapy will experience a biochemical relapse following radical treatment (2), defined by ASTRO Phoenix as a rise in PSA of 2 above the nadir (3).

Rescue brachytherapy has emerged as a potential treatment for local recurrence; the diagnosis is made following biochemical recurrence, initially via transrectal ultrasound and a positive biopsy. Once the diagnosis has been confirmed, treatment is carried out using high- or low-dose-rate brachytherapy at the local site (4). Since the late 2000s, the first retrospective studies reviewing outcomes in patients treated with rescue brachytherapy have been published; these were initially studies with a limited number of patients and short follow-up periods, reporting single-centre experience with either high-dose-rate or low-dose-rate treatment. Treatments were administered with non-uniform doses for both high-rate and low-rate brachytherapy, with fractionation ranging from a single fraction of 19 Gy up to a maximum of 4 fractions for high-rate therapy, and doses between 120 Gy and 140 Gy for low-rate therapy (without the optimal fractionation being determined in these cases). In most cases, follow-up did not extend to 3 years, with local control and biochemical control rates of between 50–70 per cent. (4, 5, 6, 7).

In recent years, series with larger sample sizes and longer follow-up have been published, although no consensus has been reached regarding fractionation schemes and the techniques used. Retrospective studies have compared both techniques, yielding similar results in terms of toxicity and, in some cases with 5-year follow-up, showing SLRB rates of up to 70 per cent (50–70 per cent). (8, 9).

To assess prognostic factors, the first Spanish multicenter retrospective study (4) was published in 2014, which included patients treated with both high-dose and low-dose regimens, who had previously undergone external beam radiotherapy up to a maximum of 78 Gy or initial LDR, and who had a diagnosis of biochemical relapse according to the Phoenix criteria and a positive biopsy. Prognostic factors were analyzed in a total of 56 patients, revealing a PSA level greater than 10 at diagnosis, a BED of less than 127 Gy and a treatment interval of less than 24 months as prognostic factors for biochemical relapses.

Following the publication of retrospective studies, two prospective studies were published: the first was a high-dose study involving only 15 patients treated with high-dose brachytherapy (5), and subsequently a study with a sample size of over 100 patients treated with low-dose brachytherapy, with a mean follow-up of 6.7 years (10). The primary endpoint of this study was genitourinary toxicity, with grade ≥3 observed in 14 per cent of patients. Regarding 10-year overall survival (OS), this stands at 70%, considering the limited patient characteristics (local recurrence confirmed by biopsy >30 months after EBRT, with prostate-specific antigen <10 ng/mL and no regional or distant disease).

Since these studies were published, the diagnosis of relapse following radical treatment has evolved with the use of choline PET, which has greater sensitivity for the prostate than fluorodeoxyglucose (11–12).

With the development of choline PET, series have been published analyzing the sensitivity of choline PET as a function of PSA levels, with sensitivity figures reaching 62% between 1 and 2 and up to 73% between 2 and 3. (11).

Choline-PET enables the early diagnosis of local relapses and has changed the diagnostic pattern for relapses; it is currently the standard diagnostic method, as it allows for an accurate diagnosis of relapse and facilitates targeted biopsy (12).

Thus, to date, rescue brachytherapy has been proposed as a possible treatment for local relapses following external beam radiotherapy and/or brachytherapy, with the standard diagnostic work-up comprising MRI, PET and a prior positive biopsy. In recent years, many centers in Spain have begun to carry out these treatments systematically, although no prospective studies on high-dose brachytherapy with an adequate sample size have been published at either international or national level, as has been the case for low-dose treatment with the study by J. Crook (5).

In 2023, the Delphi consensus on salvage treatment with brachytherapy was published, showing that high-dose brachytherapy was the preferred treatment for over 70 per cent of respondents (70 per cent); with regard to the treatment dose, the accepted fractionation regimens range from a single dose of 19 Gy in a single fraction to 2 fractions of 22–27 Gy, 3 fractions of 10 Gy and 4 fractions of 8 Gy (13).

3. Study hypothesis

We propose a prospective, observational, multicenter study to analyze the treatment of prostate recurrence diagnosed using next-generation techniques (Choline PET / PSMA PET), MRI and a positive biopsy, treated with two fractions of high-dose-rate brachytherapy.

4. Objectives:

The objectives of this prospective, multicenter study are:

- Primary:

1. Biochemical relapse-free survival, defined as the time to biochemical relapse (Nadir plus 2 — Phoenix criterion)

- Secondary endpoints:

1. Local relapse-free survival: defined as the time from treatment to local relapse as detected by imaging (Choline PET/MRI).
2. Analysis of acute and chronic toxicity.
3. Study of patients' quality of life before and after treatment, to analyze the impact that local re-irradiation may have on a patient's daily life.

5. Study type

Prospective, multicenter, observational study.

6. Materials and methods

6.1 Scope of the study

This is a prospective, multicenter, observational study designed to obtain data on biochemical relapse-free survival (BRFS) and local relapse-free survival in patients treated with rescue brachytherapy in Spain, as well as data on toxicity and quality of life, using quality-of-life questionnaires, in patients undergoing a rescue brachytherapy procedure that forms part of routine clinical practice.

6.2 Definition of study subjects

Patients treated with radiotherapy with curative intent as first-line treatment (brachytherapy alone, external beam radiotherapy or external beam radiotherapy plus a brachytherapy boost) who have been diagnosed with a local recurrence using next-generation techniques (choline PET / PSMA PET) and a prior biopsy, and who are due to undergo rescue brachytherapy as part of routine clinical practice.

6.3 Selection and exclusion of subjects:

- Inclusion criteria following assessment of the patient by a multidisciplinary tumor board:
  - Aged 18 years or over.
  - Patients diagnosed with local recurrence based on next-generation imaging and a positive biopsy.
  - Hormone-sensitive patients.
  - Patients treated initially with brachytherapy alone, external beam radiotherapy, or external beam radiotherapy with a brachytherapy boost to the prostate.

- Exclusion criteria:
  - Metastatic disease.
  - Castration-resistant prostate cancer, as defined by the EAU (European Association of Urology): Patients who progress despite maintaining testosterone levels within the castration range (testosterone <50 ng/dl or <1.7 nmol/l) with at least one of the following factors: Three consecutive rises in PSA (Prostate-Specific Antigen), one week apart, representing two 50% increases from the nadir, with a PSA greater than 2; PSA progression despite successive hormonal interventions; Progression of bone lesions: progression or appearance of two or more bone lesions, or progression in soft tissues according to the criteria for assessing response in solid tumors (RECIST criteria).

6.4 Identification and recruitment of participants

The principal investigator will recruit patients from the Radiation Oncology clinic, and the trial will be offered to patients attending their first consultation for rescue brachytherapy treatment.

6.4.1 Data collection:

Data will be collected using the SERGAS REDCAP system.

6.5 Allocation/randomization procedure: N/A

6.6 Justification of sample size

Sample size calculations were based on the primary endpoint, 'biochemical relapse-free survival'. Based on the literature, a biochemical relapse rate of 40 per cent is expected, with a median time to relapse of 33 months (6–48 months), according to the study 'Salvage Low-Dose-Rate Prostate Brachytherapy: Clinical Outcomes of a Phase 2 Trial for Local Recurrence after External Beam Radiation Therapy' (NRG Oncology/RTOG 0526). Assuming an

exponential failure rate, a Type I error of 0.05, a statistical power of 80 per cent and a dropout rate of 20 per cent, the required sample size is 63 subjects.

6.7 Primary and secondary variables

- VARIABLES TO BE ANALYSED:

PRE-TREATMENT.

- Age at initial diagnosis and at diagnosis of relapse.
- Personal history.
- Family history.
- Treatment for initial LUTS.
- Initial PSA.
- Date of initial biopsy.
- Initial diagnostic stage.
- Gleason score at initial diagnosis (current prognostic group) – Affected lobes.
- Number of biopsy cylinders. Number of positive cylinders.
- Initial diagnostic tests (CT, bone scan, MRI, choline PET, PSMA PET).
- Initial treatment prior to radiotherapy.

LOCAL RECURRENCE PRIOR TO RESCUE BRACHYTHERAPY:

- Date of diagnostic imaging tests at the time of relapse (CT, bone scan, MRI, choline PET, PSMA PET).
- PSA at the time of imaging diagnosis (prior to brachytherapy).
- PSA doubling time in the last year prior to rescue brachytherapy.
- Location of the relapse as determined by imaging.
- Date of recurrence biopsy.
- AP location of recurrence.
- IPSS at the time of relapse.
- Pre-treatment urinary symptoms.
- Date of high-dose-rate brachytherapy implantation.

DURING TREATMENT:

- Start and end dates of the initial treatment.
- Radiotherapy dose and fractionation in the initial treatment: 2 × 13 Gy.
- Hormone therapy for 6 months.

FOLLOW-UP:

- PSA levels following the initial treatment: 1 month, and then every 6 months, up to 4 years, at which point the study ends.
- Acute and chronic toxicity in the patient according to CTCAE v5.
- Date of biochemical PSA relapse (Phoenix criteria).
- Date of relapse confirmed by imaging.
- PSA at the time of imaging-based diagnosis.
- PSADT in the year prior to diagnosis by imaging.
- Site of relapse.

- Treatment following relapse.
- Acute toxicity according to the CTCAE v5.0 scale.
- Quality-of-life assessments carried out every 6 months at follow-up:
IPSS, FACT-P, EORTC QLQ-PR25 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Prostate Module), for the study of quality of life.

6.8 Description of the intervention

PROTOCOL AND WORK PLAN:

-FIRST CONSULTATION:

During the first consultation, the following must be confirmed:

- Physical examination.
- Diagnosis of local recurrence by choline PET and MRI within 3 months prior to the consultation.
- Diagnosis by biopsy within the last 2 months prior to the first consultation.
- PSA test carried out within the last 2 months prior to the consultation.
- Confirm that the patient meets the inclusion criteria.
- Signing of the informed consent forms.
- The following tests will be carried out at the first consultation:

------ IPSS.

------ FACT-P.

------ EORTC QLQ-PR25 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Prostate Module).

-BRACHYTHERAPY PROCEDURE:

The procedure will be carried out using a high-dose-rate system in two fractions of 13 Gy, administered 15 days apart, to be performed within two months of the initial consultation and the signing of the consent forms.

The patient will receive concomitant treatment with hormonal blockade lasting 6 months, which will not exceed the 6 months prior to the implantation.

Treatment will be administered to the entire gland.

MRI fusion is not mandatory, although it may be used.

The dosimetry criteria that the implant must meet are as follows, in accordance with the European guidelines on brachytherapy:

- Dosimetry criteria for the implant:

--- Prostate. Prostate volume not exceeding 60 cc, V100 ≥ 95%, V150 < 55%, D100 > 80%,

--- Urethra: D1cc < 160 per cent, D10 per cent < 150 per cent, D30 per cent < 130 per cent.

--- Rectum: 70 per cent of the dose within a volume of <1 cc.

-FOLLOW-UP:

-- FIRST FOLLOW-UP APPOINTMENT (in accordance with standard clinical practice): One month after brachytherapy, a PSA blood test will be carried out.

Quality of life assessments and toxicity monitoring (CTCAE version 5) will be carried out.

--FURTHER FOLLOW-UP (in accordance with standard clinical practice):

Follow-up will take place: 1 month after treatment, and then every 6 months, up to 4 years, with a PSA test (at which point the study ends), as well as the completion of the IPSS, FACT-P and EORTC QLQ-PR25 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Prostate Module) quality of life assessments and CTCAE version 5 at each consultation.

Biochemical relapse will be assessed according to the Phoenix Criterion (PSA nadir plus 2).

In the event of a biochemical relapse, an NGI scan will be performed to assess whether the disease is localized, pelvic or distant.

6.9 Timetable and expected completion date.

The anticipated duration of patient recruitment from the date of approval by the Ethics Committee will be 2 years; thereafter, patients will be followed up in accordance with standard clinical practice until 4 years have elapsed from the start of the study for the final statistical analysis.

6.10 Statistical analysis plan

For data analysis, a descriptive analysis of the data will be carried out. Qualitative variables will be presented as absolute frequencies and percentages. Quantitative variables will be presented as means and standard deviations.

A univariate analysis will be carried out to determine the variables that could have an effect on local relapse-free survival and biochemical relapse-free survival (age at diagnosis, initial radiotherapy dose, dose and fractionation in relapse treatment, PSA at diagnosis of relapse, and site of local relapse), as well as those that may influence the early diagnosis of local relapse (PSA at diagnosis of relapse, PSADT at diagnosis of relapse). The chi-squared test will be used to compare qualitative variables, and the Student's t-test will be used to compare quantitative variables.

A level of statistical significance of $p < 0.05$ is set.

Survival, local relapse-free survival and biochemical relapse-free survival will be assessed using the Kaplan-Meier method. The study will begin with a univariate analysis to determine whether any individual relationships exist, using the Log-Rank test. This will be followed by a multivariate analysis using Cox regression, incorporating those variables that showed a significant value in the univariate analysis.

7. Ethical and legal considerations

7.1 Compliance with Good Clinical Practice guidelines, the Declaration of Helsinki, the Oviedo Convention, as well as data protection regulations, medical record management and other applicable regulations depending on the type of study.

The study will be conducted in accordance with the Good Clinical Practice guidelines issued by the International Conference on Harmonisation (ICH) and with the Declaration of Helsinki and its subsequent revisions (version updated at the General Assembly in October 2024). All study procedures will be carried out in accordance with the provisions of the Biomedical Research Act 14/2007.

Prior to the commencement of the study, documented approval will be obtained from the relevant body (Research Ethics Committee). Where necessary, an extension, amendment or renewal

of the committee's approval. Each center will be responsible for obtaining an exemption from consent in those cases where this is deemed appropriate.

Written informed consent will be obtained from the patient prior to the collection of any data.

The confidentiality of patients' data will be respected, in compliance with current legislation on the protection of personal data (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of personal data (GDPR) and Organic Law 3/2018 of 5 December on the protection of personal data and the guarantee of digital rights).

Informed consent will be obtained by the oncologists from the participating radiotherapy oncology departments, following an explanation of the study and verification that the patient can understand it.

It will be clearly explained that there is no additional risk associated with participating in this study, as the information used for the study is obtained from the routine follow-up carried out in such cases as part of daily clinical practice at our center.

7.2 Informed consent forms: Attached.

7.3 Confidentiality of information collected in the context of the study.

DATA COLLECTION AND ANALYSIS:

The variables will be recorded by entering them into a database that complies with current legislation on the protection of personal data (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on data protection (GDPR) and Organic Law 3/2018 of 5 December on the protection of personal data and the guarantee of digital rights). Access to the RED CAP network will be provided to all collaborators for the purpose of data collection.

Only those data from the medical records that are relevant to the study will be collected. This access to and collection of data from the database will take place in the presence of the Principal Investigator/Collaborating Investigators, who are responsible for ensuring the confidentiality of all data from the medical records belonging to the subjects participating in the clinical trial.

Such personal data will undergo a process of pseudonymization/encoding.

The data will be sent to the Sponsor, who will retain it for the study for the entire duration of the trial and, following its completion, for at least the period stipulated by current legislation.

7.4 Handling of biological samples in accordance with Act 14/2007 and Royal Decree 1716/2011: N/A

7.5 Insurance policy or justification for its absence for experimental studies: N/A

7.6 Commitment to publish the results

The principal investigator and collaborating investigators undertake to make the results of the research study public, whether positive or negative.

8. Financial report and source of funding

The project has been awarded an IRAD-FEOR grant (Spanish Society of Radiation Oncology) for the development of prostate cancer research projects (2024 call for proposals) amounting to 40,000 euros.

This is a non-profit study conducted within the framework of standard clinical practice, in which neither the researchers nor the sponsor will receive any financial remuneration. The project will be carried out using the funding provided by this grant, without recourse to additional resources. No collaboration with any private entity is envisaged for the funding of this project.

The grant budget will be used to develop an electronic data collection form, to manage and monitor the data and to finalise the study, to manage documentation, to review the data included in the CRD and to publish the results of the study.

This study may be considered a non-commercial clinical trial* and is therefore exempt from evaluation fees, as it meets the following conditions:

- *The sponsor is IRAD (Institute for Research in Radiation Oncology), SEOR (Spanish Society of Radiation Oncology).*
- *Ownership of the research data belongs to the sponsor from the outset of the study.*
- *There are no agreements between the sponsor and third parties that permit the use of the data for regulatory purposes or that give rise to industrial property rights.*
- *The design, conduct, recruitment, data collection and reporting of research results remain under the sponsor's control.*
- *Due to their nature, these studies do not form part of a development programme for the marketing authorization of a product*

** Article 2.2 of Royal Decree 1090/2015 of 4 December, regulating clinical trials with medicinal products, Ethics Committees for Research Involving Medicinal Products and the Spanish Register of Clinical Trials, and Article 2.2 of Royal Decree 957/2020 of 3 November, regulating observational studies involving medicinal products for human use.*

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10. Electronic Data Capture

An electronic data capture will be provided via the Red Cap network, to which participating hospitals will have access.