Please observe: Ability to understand Swedish in written and spoken form are inclusion criteria for participation in PARIS-BIO. Below is an LLM-rendered, non-approved translation into English of the information sheet and consent form for PARIS-BIO.

Participant Information – Clinical Trial

EU Trial Number: 2025-520639-17-00

Trial Title: PARIS-BIO: Biomarker to Predict Shrinkage of Prostate Cancer with Nubeqa

Version: 2.0, 2026-02-17

Information for Participants

We would like to ask you to participate in a clinical trial. This document explains the study, what participation involves, and potential risks and benefits.

Purpose of the study

This study investigates whether a biomarker (PCAI ImmunoScore) can predict which prostate cancers respond best to preoperative treatment with Nubeqa. The goal is to individualize treatment and improve outcomes while minimizing unnecessary side effects and costs.

Study conduct

If you participate, you will take Nubeqa (2 tablets morning and evening) for 90–120 days before radical prostatectomy. After about 90 days, an MRI will be performed. Surgery occurs within 120 days.

Blood samples are taken before treatment, during treatment (1–3 months), and after surgery (3 and 12 months). You will also complete 5 digital questionnaires over 16 months.

After surgery, prostate tissue will be analyzed. Existing biopsy samples will also be analyzed to calculate PCAI ImmunoScore.

Participants

100 men with high-risk prostate cancer will participate. If you decline, you receive standard treatment without Nubeqa.

Risks and disadvantages

Possible side effects include fatigue, breast swelling, hot flashes, and high blood pressure. Surgery may be delayed up to 2 months, with a small risk of tumor progression.

Genetic analyses will generally not be reported unless clinically relevant.

Data handling

Your medical and study data will be pseudonymized and stored securely. Data may be shared within Sweden and the EU/EEA. You cannot be identified in study results.

Your rights

You may access, correct, or request deletion of your data (with some limitations for research). Complaints can be made to the Swedish Authority for Privacy Protection.

Quality control and storage

Authorized personnel may review your medical records. Data will be stored for 25 years.

Samples

Blood samples are discarded after analysis. Tissue samples are stored coded in a biobank for up to 10 years and may be analyzed within the EU/EEA. You may withdraw consent and request destruction of samples.

Results

Results will be published in scientific journals and EU databases. Only aggregated data will be presented.

Insurance and compensation

You are covered by patient and pharmaceutical insurance. Participation is unpaid but also cost-free.

Voluntary participation

Participation is voluntary and can be withdrawn at any time without affecting care.

Responsible investigators

Principal Investigator: Professor Peter Wiklund, Karolinska University Hospital.

Consent

By signing, you confirm you understand the study, consent to participation, data handling, and storage of samples, and acknowledge your right to withdraw at any time.