A Randomized Comparison of PSA and Stockholm3 for Early Detection of Prostate Cancer

conducted at

Capio Proximity Care in Sweden

in cooperation with

Karolinska Institutet, Stockholm, Sweden

Study protocol

* * *

Acronym: COMPASS
Version: 1.0
Date: March, 2025

Table of Contents

Background

Prostate cancer constitutes about 15 % of new cases of cancer among men globally. Early diagnosis of prostate cancer is associated with significantly better treatment outcome and reduced prostate specific mortality [1]. There are usually no clinical manifestations of prostate cancer until the disease is more advanced, which means that prostate cancer can only be detected early by screening with blood markers such as PSA (prostate specific antigen) or by imaging with Magnetic Resonance Imaging (MRI).

Results from the European Randomized Study of Screening for Prostate Cancer (ERSPC) showed that PSA screening was associated with a 21% relative reduction in the risk of dying from prostate cancer at a median follow-up of 11 years [2].

Prostate cancer screening typically begins with a PSA test. If the PSA is elevated, commonly defined as PSA ≥3 ng/ml, the man is usually referred for further investigation with magnetic resonance imaging (MRI). If the MRI shows abnormalities, i.e. PIRADS ≥ 3, the man should undergo a prostate biopsy followed by pathological evaluation of the biopsy specimen. The pathologist assigns a Grade Group to the biopsy sample. If the Grade Group is ≥ 2 the man is diagnosed with clinically significant prostate cancer (csPC) and should receive appropriate treatment if possible.

PSA testing is controversial due to its low specificity and association with benign prostatic hypertrophy seen in 50% of men aged 50-60 and 80% in men over 70 years [3]. As a result, several adjunct diagnostic tests have been developed to improve detection of csPC and enhance performance of prostate cancer testing. Examples of these tests include 4K Score (OPKO Health Inc.), phi (Beckman Coulter), and Stockholm3 (A3P Biomedical AB). Many of these tests have shown promising results in reducing unnecessary follow-up procedures, such as MRIs and biopsies.

PSA testing is also missing lethal cancers below traditional thresholds (≥ 3 ng/ml), where contemporary evidence now supports a ‘U’ shaped PSA distribution for csPC with many men harbouring lethal cancer at lower PSA [4]. Some biomarkers, like Stockholm3, have shown potential for earlier detection of csPC particularly in men with low PSA values who might not otherwise be identified. However, despite these advances, none of the adjunct tests are currently recommended in clinical guidelines due to the absence of high-quality randomized studies confirming their clinical utility compared to current standard of care.

Stockholm3 is a multiparametric blood test combining protein-, genetic and clinical markers to predict the risk of csPC. Studies have shown that Stockholm3 can improve prostate cancer detection if it is used as an adjunct test to PSA ≥1.5 ng/ml [5-7]. Earlier studies have shown that Stockholm3 as a reflex to PSA ≥ 1.5 ng/ml increases the detection of csPC by ≥ 20% vs

PSA in a controlled clinical trial [5] and that Stockholm3 as a reflex to PSA 1.5 ng/ml increases the detection of csPC by ≥ 40% vs PSA in a clinical utility setting [6].

Both PSA and Stockholm3 are currently used as part of clinical practice in Sweden. PSA testing is available through various laboratories, including Karolinska University Laboratory, Akademiska Sjukhuset, and Unilabs. Stockholm3 is available through Unilabs.

Study Objectives

The main objective of this randomized study is to evaluate the diagnostics performance of standard of care for prostate cancer testing using PSA (control arm) vs an experimental arm using Stockholm3 as a reflex if PSA ≥ 1.5 ng/ml in routine clinical care in a primary care setting in Sweden.

Primary endpoint measures

- Number of csPC, defined as Grade Group ≥ 2

Secondary endpoints measures

- Investigator compliance with diagnostic test outcome, e.g. if the ratio of men with PSA ≥ 3 ng/ml or Stockholm3 ≥11 referred to MRI or biopsy for further testing
- Number of MRIs performed
- Outcome in MRI, i.e. PI-RADS score
- Number of biopsies performed
- Number of benign biopsies
- Number of Grade Group 1 cancers
- Number of Grade Group ≥ 3 cancers
- Prostate cancer deaths
- Deaths due to any cause

Study design

This is a prospective, multicenter, randomized clinical trial where clinical utility and diagnostic test performance of PSA and Stockholm3 will be evaluated in two phases, Phase I and Phase II.

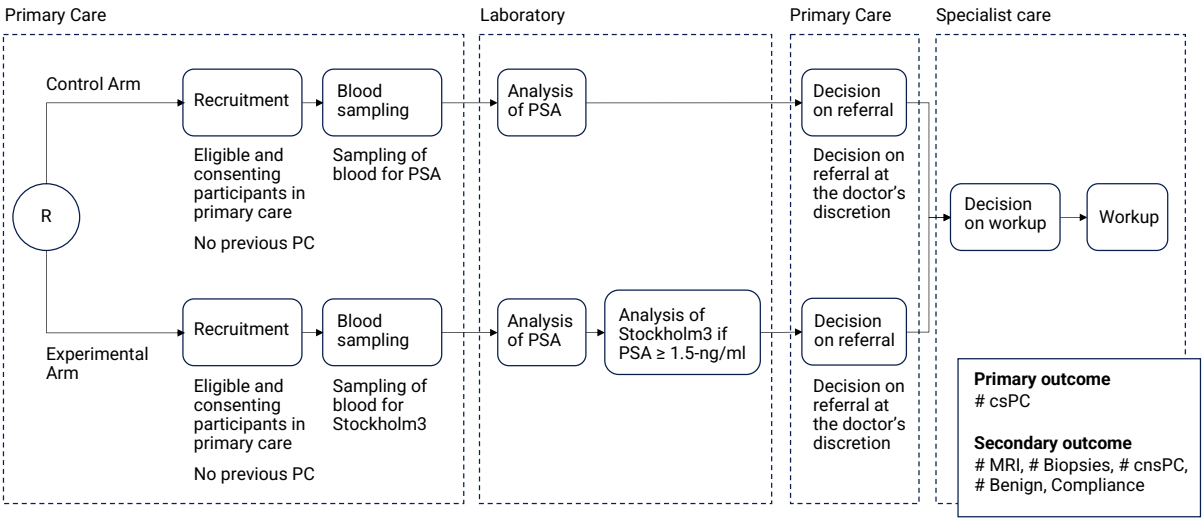
Phase I design

Phase I will compare the clinical utility of using PSA based diagnostics versus using Stockholm3 as a reflex to PSA ≥ 1.5 ng/ml. Participating primary care units will be 1:1 cluster

randomized between control arm with standard of care (SOC) with PSA or experimental arm with Stockholm3 as a reflex to PSA ≥ 1.5 ng/ml. Cluster randomization was chosen for this study phase to prevent potential contamination between intervention and control groups. Individual randomization could lead to participants in the control arm unintentionally receiving components of the intervention through interactions with participants in the intervention group. We hypothesize that the use of Stockholm3 improves both test characteristics and the operational structure in the healthcare system (e.g. compliance with test recommendations) compared with today's standard of care. While the effect of better test characteristics is possible to study using individual randomization (see Phase II), the improved operational structure requires cluster randomization to avoid spill-over effects. By randomizing at the cluster level, we thus ensure clearer separation between treatment arms to study the *combined* effect of test characteristics and operations.

This study phase is unblinded for both investigators and participants. Participating primary care units will be cluster-randomized at the study start to either the control or experimental arm. Primary care physicians will recruit men they consider eligible for prostate cancer testing, following standard clinical practice. The decision to refer participants for specialist evaluation, including MRI and biopsy, will be made by the primary care physician in accordance with standard clinical practice

Figure 1: Phase I design overview

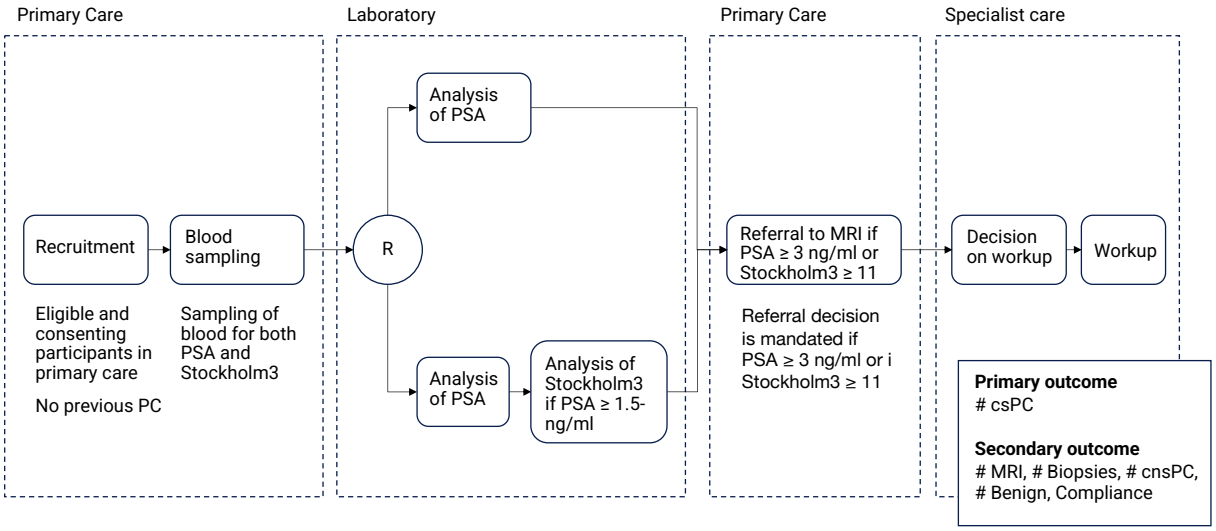


Phase II design

Phase II will compare the diagnostic test performance of Stockholm3 (as a reflex to PSA ≥ 1.5 ng/ml) to using PSA only. Participants will be 1:1 randomized between control arm with PSA and experimental arm with Stockholm3 as reflex to PSA ≥ 1.5 ng/ml. For Phase II, we are thus interested in comparing the test characteristics in isolation (i.e. not Stockholm3's effect on operations, e.g. compliance) and we therefore use randomization on an individual level.

This study phase includes delayed unblinding, meaning that both investigators and participants will remain blinded at the time of blood sampling and will only be unblinded upon receiving the test results. Primary care physicians will recruit men they consider eligible for prostate cancer testing, following standard clinical practice. All participants will undergo blood sampling for both PSA and Stockholm3. Randomization will be performed at the laboratory, and only the assigned test will be analyzed. Men with PSA ≥ 3 ng/mL (standard of care) or Stockholm3 ≥ 11 will be required to undergo further evaluation with MRI.

Figure 2: Phase II design overview



Study population

Inclusion criteria

- Men eligible for prostate cancer testing, as determined by their physician
- Age ≥ 40 years

Exclusion criteria

- Previous diagnosis of prostate cancer
- Cognitive disabilities unable to understand study information material

Study size and outcome

Phase I

We assume individual randomization and an effect size of a 40-50% increase in csPC detection (4% in the control arm vs. 5.6-6.0% in the experimental arm), a 5% significance level, 80% power, an average sample size per cluster of *m*=100-150 men, and an intracluster correlation coefficient (*ICC = Between-cluster variance / (Between-cluster variance + Within-*

cluster variance) of 0.005-0.01. The ICC measures how similar outcomes from individuals within the same cluster are, compared to individuals from different clusters. It thus quantifies the extent to which outcomes "cluster together" within participating sites. Following Rutterford et al. [8], a sample size of 8,000 men then provides in the range of 58-92% power. Specifically, using plausible values of an effect size of 45%, *m*=100, and an ICC of 0.008 gives 80% power with 8,000 recruited men.

Phase II

The sample size is based on a superiority trial design to detect a 20% increase in csPC detection (4% in the control arm vs. 4.8% in the experimental arm). With a 5% significance level, 80% power, and a 1:1 randomized design, the required sample size is 10,856 participants per group (adjusted for 5% dropout), totalling 21,712 participants.

Randomization procedure

Recruitment will take place at more than 30 primary care units across Sweden. To participate in the study, primary care units must use Unilabs as their laboratory service provider.

Phase I

Participating primary care unit will be 1:1 cluster randomized at study start to one of two study arms:

- Control arm: standard of care with PSA-based diagnostics
- Experimental arm: Reflex testing to Stockholm3 if PSA ≥1.5 ng/ml

To ensure balanced allocation between study arms, stratified block randomization is employed with strata defined by:

- Socioeconomic status (CNI, Care Need Index) of the participating site's catchment area (low, medium, high)
- Annual PSA testing volume at the participating site (low, medium, high)

Primary care units are identified and randomly assigned to a study arm using a centralized, computer-generated randomization list. The randomization is performed by an independent statistician who is not involved in the recruitment process.

Phase II

Each referral is automatically assigned a referral identity number (RID) by the laboratory consisting of 8 digits. If the sum of numbers in the RID is even, the man is randomized to the control arm, if the sum of numbers in the RID is odd the man is randomized to the experimental arm. Given that RIDs are assigned consecutively by the laboratory for all the analyses in Sweden, the sum of numbers in the RID will be 50% odd and 50% even.

Study participants will be followed up at 2, 4 and 6 years following the recruitment.

Participation in the study and informed consent

Each research participant will, after reading the *Research Participant Information*, sign an informed consent, either on paper or electronically.

Data Collection

		Phase I		Phase II	
Data collected	Sample space	Control	Experiment	Control	Experiment
Age	Integer	X	X	X	X
Family history of prostate cancer	Yes No Not known		X	X	X
Use of 5-alfa reductase inhibitors	Yes No Not known		X	X	X
Earlier negative biopsy conducted with the last 12 months	Yes No Not known		X	X	X
Date of blood sampling	Date format	X	X	X	X
Date of test result report	Date format	X	X	X	X
Stockholm3 Risk Score	Integer [1-99]		X		X
PSA value	Float [0-9,999]	X	X	X	X
Digital Rectal Examination	Positive Negative Not known	X	X	X	X
MRI conducted*	Yes No	X	X	X	X
Date of MRI (only if MRI conducted)	Date format	X	X	X	X
PIRADS (only if MRI conducted)	1 2 3 4 5	X	X	X	X
Prostate volume and other data from MRI report (only if MRI conducted)	Text	X	X	X	X
Biopsy conducted*	Yes No	X	X	X	X
Date of biopsy (only if biopsy conducted)	Date format	X	X	X	X
ISUP (only if biopsy conducted)	Benign 1 2 3 4 5	X	X	X	X
Percentage Gleason Score 4 (only if positive	Percentage	X	X	X	X

		Phase I		Phase II	
Data collected	Sample space	Control	Experiment	Control	Experiment
biopsy conducted)					
Cancer length (only if positive biopsy conducted)	Float [0-999]	X	X	X	X
Type of biopsy (only if biopsy conducted)	Text	X	X	X	X
Type of instrument (only if biopsy conducted)	Text	X	X	X	X
Date of PAD report (only if biopsy conducted)	Date format	X	X	X	X

Results of MRI and biopsy will be followed up at 4 months after blood test to allow for lag in radiology/pathology.

Blood handling

Phase I

Each participant in the control arm will donate 5 ml of blood (1 x 5 ml serum). Each participant in experimental arm will donate 10 ml of blood (2 x 5 ml EDTA). Blood sampling will be done by professional phlebotomists at Unilabs or at the primary care unit.

Phase II

Each research participant will donate 15 ml of blood (1 x 5 ml serum + 2 x 5 ml EDTA). Blood sampling will be done by professional phlebotomists at Unilabs or at the primary care unit.

Project description, Phase I

Step 1: Cluster randomization

Participating primary care units will be 1:1 cluster randomized to either control or experimental arm. For randomization procedure, please see section *Randomization Procedure* above.

Step 2: Recruitment, consent, and blood sampling

Men with no previous prostate cancer diagnosis, eligible for prostate cancer test according to standard of care and meeting the study inclusion/exclusion criteria, will be offered to participate in the study.

Men that are interested and have read the *Research Participant Information* will sign an informed consent. Men that are not interested to participate in the study will be offered standard of care.

The physician orders PSA (control arm) or Stockholm3 (experimental arm) from Unilabs' catalog. The research participant proceeds to the sampling unit, where blood is collected for PSA (control arm, 1 x serum tube) or Stockholm3 (experimental arm, 2 x EDTA tubes). The samples are transported to Unilabs in Solna/Huvudsta.

Step 3: Lab analysis

Samples are received at Unilabs in Solna/Huvudsta.

Samples from primary care units are processed for PSA (control arm) or PSA and Stockholm3 if PSA ≥1.5 ng/ml (experimental arm) and the result is reported to the ordering physician.

Step 4: Clinical decision based on lab results

Based on the result from the PSA or Stockholm3 analysis, the man is handled in accordance with clinical practice at the participating primary care unit. This means that the doctor will take decision whether to send men with elevated PSA (PSA ≥ 3 ng/ml, control arm) or elevated Stockholm3 (Stockholm3 ≥ 11, experimental arm) for further examination with MRI Men with positive MRI (PIRADS ≥ 3, both arms) should be offered prostate biopsy based on current standard of care.

Step 5: Data collection

Data will be collected prospectively by medical record analyses to see if the man was referred to MRI and/or prostate biopsy, and if so, the results from these procedures (Grade Group and PIRADS) will be collected. Unilabs will provide a list of all PSA tests at participating primary care units. Data on percentage of Gleason Grade 4, mm cancer, type of biopsy, instrument used will be collected from analyses of pathology reports. Data on type of MRI protocol and MRI instruments will be collected from analysis of radiation reports.

Karolinska Institutet will enter data into a study database and evaluate the results.

MRI and biopsies performed within 4 months from test results delivered to physician will be included in the analysis.

Step 6: Statistical analysis

A Statistical Analysis Plan (SAP) will be developed and published before the start of the study. In summary, we will apply the following statistical analyses:

Primary outcomes:

- We will use a generalized linear mixed model (GLMM) with a log-link function and binomial distribution test to for differences in detection rates of csPC. Mixed effect models explicitly incorporate cluster-level random effects, ensuring accurate estimation of intervention effects and their standard errors. Results will be presented as risk ratios (RRs) or risk differences (RDs) with corresponding confidence intervals, adjusting for randomization stratification variables. Cluster-level random intercepts will account for within-cluster correlations. In the event of convergence issues, a modified Poisson regression model with robust standard errors will be used as a backup strategy.

Superiority testing will be conducted to assess whether the Stockholm3-based diagnostic pathway detects a significantly higher number of clinically significant prostate cancers (csPC) compared to the standard PSA-based pathway. The null hypothesis (H_0) assumes that both diagnostic strategies have equal detection rates, whereas the alternative hypothesis (H_1) assumes that the Stockholm3 pathway results in a higher detection rate. 95% confidence intervals for effect size estimates will be reported.

- Socioeconomic status (CNI, Care Need Index) of the participating site's catchment area (low, medium, high)
- Annual PSA testing volume at the participating site (low, medium, high)

Secondary outcomes:

- A generalized linear mixed model (GLMM) with a log-link function and binomial distribution to test for differences in compliance
- Descriptive statistics for MRI and biopsy rates
- Detection of clinically significant prostate cancer at different PSA ranges
- Operating characteristics of PSA and Stockholm3 to predict csPC at different PSA and Stockholm3 cut-offs
- Operating characteristics of PSA and Stockholm3 to predict abnormal MRI (defined as PIRADS ≥3) at different PSA and Stockholm3 cut-offs
- Operating characteristics of PSA and Stockholm3 to predict abnormal MRI (defined as MRI that led to csPC) at different PSA and Stockholm3 cut-offs
- Unnecessary biopsies/MRIs: a normal MRI based on prostate imaging reporting and data system (PIRADS) (I.e. PIRADS 1, 2 and without lesion), benign pathology on biopsy, or low grade ISUP 1 cancer (aka, Grade Group 1, Gleason Score 3+3, Gleason Score 6)
- Adjusted analyses based on potential confounders (e.g., age, PSA levels)
- Healthcare utilization of resources (#MRI, #Biopsy, #ISUP grade group 1 cancers detected)

Randomization stratification factors will be included as covariates in the regression models used for analysis. Data analysis will be performed by the PI or key research personnel. An independent Data Analysis Committee headed by Professor Derya Tilki will be overseeing the data analysis.

Step 7: Publication

Data is analyzed and presented as statistical data in a peer reviewed journal. Data from Phase I may be published before Phase II is started.

Data structure

The tables below lay out the general data structure. Data may be structured in the following format but will not be limited to this structure.

Table 1: Clinical characteristics and outcomes

Clinical characteristics	All (N = …)	Standard Arm	Experimental arm
Age, years (median, IQR)			
PSA (ng/ml) (median, IQR)			
DRE abnormal (N, %)			
Family history of prostate cancer (N, %)			
Previous negative prostate biopsy (N, %)			
Stockholm3 (median, IQR)			
Underwent MRI (N, %)			
PIRADS ≥3 (N, %) PIRADS ≥4 (N, %)			
Benign biopsy (N, %)			
ISUP 1 Prostate Cancer (N, %)			
ISUP ≥2 Prostate Cancer (N, %)			
ISUP ≥3 Prostate Cancer (N, %)			

Project description, Phase II

Step 1: Recruitment, consent, and blood sampling

Men with no previous prostate cancer diagnosis, eligible for prostate cancer testing according to standard of care and meeting the study inclusion/exclusion criteria, will be offered to participate in the study. The physicians at participating primary care centers will offer the men participating in the study and inform that the patient will be randomized to either a control arm with PSA or an experimental arm with PSA and Stockholm3 done as reflex test if PSA ≥ 1.5 ng/ml.

Men that are interested and have read the *Research Participant Information* will sign an informed consent. Men that are not interested to participate in the study will be offered standard of care.

The physician orders “PSA+” from Unilabs’ catalog. The analysis code for the test generates orders for two analyses: a standard PSA test and the Stockholm3 test. The research participant proceeds to the sampling unit, where three blood samples are collected: one

serum tube for PSA and two EDTA tubes for Stockholm3. All samples are transported to Unilabs in Solna/Huvudsta.

In parallel, the randomization is conducted in Unilabs' system. Each referral is randomly assigned to either the control arm (PSA diagnostics) or the experimental arm (Stockholm3 diagnostics).

Step 2: Lab analysis

Samples are received at Unilabs in Solna/Huvudsta. Referrals assigned to the control arm are processed as follows:

1. The EDTA samples are discarded
2. The serum sample proceeds to PSA analysis
3. The PSA result is reported to the ordering physician

Referrals assigned to the experimental arm are processed as follows:

1. The serum sample is discarded
2. The EDTA samples proceed to Stockholm3 analysis
3. The Stockholm3 result is reported to the ordering physician

Step 3: Clinical decision based on lab results

The man is referred to MRI by the primary care physician if PSA ≥ 3 ng/ml or if Stockholm3 ≥ 11. Men with positive MRI (PIRADS ≥3) will be offered prostate biopsy.

Step 4: Data collection

See "Step 4: Data collection, Phase I" above.

Step 5: Statistical analysis

Primary outcomes:

- We will use a generalized linear model (GLM) with a log-link function and binomial distribution test to for differences in detection rates of csPC. Results will be presented as risk ratios (RRs) or risk differences (RDs) with corresponding confidence intervals, adjusting for randomization stratification variables. In the event of convergence issues, a modified Poisson regression model with robust standard errors will be used as a backup strategy.

  Superiority testing will be conducted to assess whether the Stockholm3-based diagnostic pathway detects a significantly higher number of clinically significant prostate cancers (csPC) compared to the standard PSA-based pathway. The null hypothesis (H_o) assumes that both diagnostic strategies have equal detection rates,

whereas the alternative hypothesis (H_1) assumes that the Stockholm3 pathway results in a higher detection rate. 95% confidence intervals for effect size estimates will be reported.

- Socioeconomic status (CNI, Care Need Index) of the participating site's catchment area (low, medium, high)
- Annual PSA testing volume at the participating site (low, medium, high)

Secondary outcomes:

- Logistic regression models for compliance assessment
- Descriptive statistics for MRI and biopsy rates
- Detection of clinically significant prostate cancer at different PSA ranges
- Operating characteristics of PSA and Stockholm3 to predict csPC at different PSA and Stockholm3 cut-offs
- Operating characteristics of PSA and Stockholm3 to predict abnormal MRI (defined as PIRADS ≥3) at different PSA and Stockholm3 cut-offs
- Operating characteristics of PSA and Stockholm3 to predict abnormal MRI (defined as MRI that led to csPC) at different PSA and Stockholm3 cut-offs
- Unnecessary biopsies/MRIs: a normal MRI based on prostate imaging reporting and data system (PIRADS) (I.e. PIRADS 1, 2 and without lesion), benign pathology on biopsy, or low grade ISUP 1 cancer (aka, Grade Group 1, Gleason Score 3+3, Gleason Score 6)
- Adjusted analyses based on potential confounders (e.g., age, PSA levels)
- Healthcare utilization of resources (#MRI, #Biopsy, #ISUP grade group 1 cancers detected)
- Cox model for longer-term endpoints (prostate cancer specific mortality and overall mortality)

Randomization stratification factors will be included as covariates in the regression models used for analysis. Data analysis will be performed by the PI or key research personnel. An independent Data Analysis Committee headed by Professor Derya Tilki will be overseeing the data analysis.

Step 6: Publication

See "Step 6: Publication, Phase I" above.

Data structure

See “Data structure, Phase I” above.

Ethical considerations

Cluster randomization presents ethical challenges regarding the principles of justice and individual autonomy. Since entire primary care units are assigned to either the control or experimental arm, some patients will not have the opportunity to receive the experimental intervention, which they may perceive as a disadvantage. However, since the standard of care remains unchanged – meaning these patients would not have had access to the experimental intervention outside the study either – we do not consider this a major ethical concern.

There is a minimal risk of complications associated with the venous blood sampling, but since it is performed by highly experienced nurses, involves only a small amount of blood (15 ml), we do not believe there is a significant risk of physical discomfort.

A key ethical consideration in diagnostic studies is the risk of false negatives and false positives. False negatives may lead to delayed cancer detection and treatment, while false positives can cause unnecessary anxiety, invasive procedures, and potential complications. The experimental arm, by integrating Stockholm3 as a reflex test, is expected to reduce both false negatives – by detecting clinically significant prostate cancers at lower PSA levels – and false positives, by decreasing unnecessary MRI, thereby improving both patient safety and resource utilization.

All project data and test results will be kept anonymous on the encrypted and password protected database and will be analyzed with secure research designated computers at Karolinska Institutet to prevent unauthorized access to them. All researchers connected to the project are under confidentiality agreements. Results from the study will be presented in such a way that no individual information will be disclosed.

Approval

The project will seek approval from the Swedish Ethical Review Authority (Etikprövnings-myndigheten). Written informed consent will be obtained from all participants before enrollment.

Timeline

The study will start as soon as the project has received approval from the Swedish Ethical Review Authority. The target starting time is April 2025. The study is expected to be running until June 2026. The key connecting data to individuals will be discarded 10 years after the study ends.

Study budget

The study budget will be covered by a grant from A3P Biomedical.

Participating healthcare providers

Primary care providers in Sweden with laboratory services provided by Unilabs.

Organizational structure

Capio Primary Care

Seika Lee	MD, Regional CMO, Capio Proximity Care

Karolinska Institutet

Tobias Nordström	MD, PhD, Urologist, PI
Henrik Grönberg	Professor
Martin Eklund	Professor
Carin Cavalli-Björkman	Study nurse, coordinator
Thorgerdur Palsdottir, PhD.	Statistician, PhD
Hari Vigneswaran	MD, Urologist

A3P Biomedical funding

Ola Steinberg	VP R&D A3P Biomedical AB

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