STHLM3 Validation Study
An observational study conducted in [University Medical Center Groningen and the
Prostatce Cancer North Netherland Partners]
in cooperation with
Karolinska Institutet, Stockholm, Sweden

Published: 25-05-2018
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The aim of this study is to validate the effectiveness of the Stockholm3 test in the Netherlands setting with dutch patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON46757

Source
ToetsingOnline

Brief title
STHLM3 Validation Study

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym

Prostatecancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: blood, Prostatecancer, STHLM3 test

Outcome measures

Primary outcome

Main outcome

* Number of biopsies

Secondary outcome

Secondary outcome

* Number of biopsies with Gleason Score * 7

* Number of biopsies with Gleason Score 6

* Number of MRIs

Study description

Background summary

Prostate cancer constitutes about 15 % of new cases of cancer among men globally.
A number of risk factors have been suggested for prostate cancer, including diet and occupational exposure, but the only factors that are conclusively associated with risk are age, ethnicity and family history. Given the high prevalence of the cancer and the limited opportunities for primary prevention, it has long been expected that a good screening test would both reduce the mortality of prostate cancer and its general burden on health.

Study objective

The aim of this study is to validate the effectiveness of the Stockholm3 test in the Netherlands setting with dutch patients.

Study design

Patients who are scheduled for prostate MRI and/or prostate biopsy will be asked to donate 12 ml of blood and to answer three clinical questions. Data on patient*s PSA value as well as result from follow-up clinical care (MRI and/or biopsy) will be collected. Stockholm3 analysis will be conducted retrospectively on the blood collected.

Study burden and risks

The following ethical considerations and questions have been identified:
Is there any discomfort participating in the S3VAL?
There is a potential discomfort when the blood sample is taken. However, the blood sample will be taken by very experienced staff that are accustomed to taking blood samples.
What to do if a high-risk patient is detected in the follow-up analysis with Stockholm3 that was not taken care in the regular care?
S3VAL is an observational study, i.e. no decision on care will be taken based on the Stockholm3 test. There is however a slight possibility that men with very high risk might have been missed in regular care and that this will be detected in the follow-up data collection. If such an event would occur, you will be contacted by your doctor and receive the result from the Stockholm3 test as well as information on additional follow-up care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with no previous prostate cancer diagnosis who are scheduled for prostate MRI and/or prostate biopsy.

Exclusion criteria

Patiënt with previous prostate cancer in medical history,

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-06-2018
Enrollment:	100

Type:	Actual

Ethics review

Approved WMO Date:	25-05-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63852.042.17

Study results