

Finger prick PSA

Published: 12-05-2017

Last updated: 11-04-2024

Method comparison between venous blood PSA and fingerprick PSA.

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

Summary

ID

NL-OMON42892

Source

ToetsingOnline

Brief title

Finger prick PSA

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym

prostate specific antigen, PSA

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Afdeling AKL van het AvL

Intervention

Keyword: finger prick, PSA

Outcome measures

Primary outcome

Method comparison; regression analysis, correlation coefficient.

Secondary outcome

Determine whether patients are capable of performing a fingerprick procedure themselves.

Study description

Background summary

This research aims to perform a method comparison of the venous PSA test and a fingerprick PSA test. The latter has the potential to avoid visits to a phlebotomy department and a venipuncture, because it allows patients to perform the fingerprick sampling themselves at home.

Study objective

Method comparison between venous blood PSA and fingerprick PSA.

Study design

Method comparison between venous blood PSA and fingerprick PSA by means of linear regression analysis and correlation analysis.

Study burden and risks

Limited burden, only the finger prick procedure, and therefore limited to no risk

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

Prostate cancer patient for whom only a PSA test is requested.

Exclusion criteria

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Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2017

Enrollment: 250

Type: Anticipated

Medical products/devices used

Generic name: finger prick phlebotomy

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 12-05-2017

Application type: First submission

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 28-03-2019

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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

CCMO

ID

NL60246.031.16