Circulating tumor DNA exposure in peripheral blood using a novel process: A feasibility study.

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Therefore the objective of this study is to test the feasibility of the detection of circulating tumor DNA of a variety of tumors in peripheral blood using a novel detection process.

Ethical review	Not approved
Status	Will not start
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON46123

Source
ToetsingOnline

Brief title
Measuring circulating tumor DNA

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer, carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Quantgene inc.
Source(s) of monetary or material Support: Sponsoring door industrie

Intervention

Keyword: cancer, ctDNA, feasibility study

Outcome measures

Primary outcome

The main study endpoint is sensitivity and specificity of the novel ctDNA

detection process.

Secondary outcome

Not applicable

Study description

Background summary

Currently, malignant organ tumors are usually detected in a later stage with a missed chance for a long-term cure. Therefore it is desirable to detect cancers at early stages. Circulating tumor DNA (ctDNA) may serve as *liquid biopsy* for detection, monitoring an potentially therapeutic decision making in certain types of cancer. The method for detection has thus far been unreliable, however a novel process has been developed, which allows detecting a wider set of mutations at a higher sensitivity then conventional sequencing-based methods.

Study objective

Therefore the objective of this study is to test the feasibility of the detection of circulating tumor DNA of a variety of tumors in peripheral blood using a novel detection process.

Study design

Prospective case-matched cohort study comparing patients with cancer with patients without a diagnosis of cancer.

Study burden and risks

Patient who choose to enter the study will have an additional blood sample taken during a regular blood withdrawal moment, as part of the offered

treatment: surgery or (radio)chemotherapy. A possible risk might be that a minor complication (hematoma, infection) due to the blood withdrawal will partake. However, since the extra blood sample is taken during a regular blood withdrawal moment, there is no additional risk when participants partake in this study.

Contacts

Public
Quantgene inc.

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Scientific
Quantgene inc.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects of both cohorts must:
- Be of age * 18 years
- Provide written consent for study participation;Subjects of cohort 1 must:
- Have a diagnosis of one of the following malignancies in clinical stage 0 to IV: non-small lung cancer, gastric cancer, pancreatic adenocarcinoma, hepatocellular carcinoma, colorectal

cancer, bladder cancer, prostate cancer, breast cancer, ovarian cancer, cervical cancer, adrenocortical cancer, breast cancer, ovarian cancer, cervical cancer, adrenocortical cancer, melanoma and leukemia.;Subjects of cohort 2 must:
- Are planned for surgery in the foreseeable future, to guarantee a blood sample.

Exclusion criteria

Subjects of cohort 1 must not:
- Have been treated for above diagnosed malignancy ;Subjects of cohort 2 must not
- Have been diagnosed or treated for a malignancy previously

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	500
Type:	Anticipated

Ethics review

Not approved

Date:	11-01-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT03517332
CCMO	NL66804.100.18