

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 and 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 than 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

Patients 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

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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 \geq 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

3 - Circulating tumor DNA exposure in peripheral blood using a novel process: A feas ... 24-05-2025

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 |