Feasibility of circulating tumour DNA (ctDNA) analysis using automated capillary blood sampling

Published: 30-04-2025
Last updated: 10-05-2025

The primary objective of the study is to determine the technical feasibility of ctDNA detection in small volumes of capillary blood. This will be investigated through determining the agreement between ctDNA measurements in venous (standard blood…

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON57457

Source
ToetsingOnline

Brief title
Automatic capillary blood withdrawal for ctDNA analysis: ctDNA TAP

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
colon cancer, Colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Capillary sampling, Colorectal Cancer, ctDNA, Tumour marker

Outcome measures

Primary outcome

The primary endpoint of the study is the agreement between ctDNA measurements

in venous versus capillary blood to determine the feasibility of ctDNA analysis

through automated capillary blood sampling.

Secondary outcome

Next to agreement, we will also determine the correlation between ctDNA levels

in venous and capillary blood.

Study description

Background summary

Aging of the general population results in an increasing number of patients who need to be cared for by a decreasing number of health care professionals. To ensure sustainable and patient-centred health care in the near future, we need to rebalance hospital-based and home-based care. Following surgery of a primary tumour or metastases thereof, patients are offered blood-based follow-up in the hospital, which is necessary to detect recurrence but represents a major burden on the current health care system. The more recently discovered, highly specific circulating tumour-derived DNA fragments (ctDNA) have high potential as a new biomarker and clinical implementation of ctDNA in CRC patient care is expected in the future. However, feasibility of ctDNA detection in blood collected through automated capillary sampling had not yet been investigated.

The adoption of home-based oncology care offers several societal and economic advantages, especially in the long-term. Firstly and most importantly, bringing this type of care closer to a patient*s home has the advantage of patient empowerment and the potential to increase quality of life and satisfaction during oncological follow-up. Additionally, it has the capacity to make surveillance strategies more cost-effective. Follow-up after curative treatment of cancer consists of several years of surveillance and multiple blood and

imaging tests. The outpatient clinic visits with blood testing account for a substantial part of the expenses in oncological follow-up. A previous study has already shown that the lancet sampling technique for chronic care patients reduces the overall societal costs per patient. Novel, painless techniques like the TAP, an automated capillary sampling device, continue to gain interest of manufacturers and, therefore, expenses are expected to drop in the future. Additional to reducing healthcare costs, home-based sampling will alleviate hospital pressure and reduce the demand on healthcare workers, particularly important in times of ever-increasing healthcare demands.

Finally, it provides benefits on an environmental level by reducing the need for patients to travel to healthcare facilities. For now, CEA is still the standard of care biomarker investigated in patients who have been treated for colorectal cancer. However, it remains a relatively non-specific serum biomarker that is elevated in various malignancies, but may also be elevated in the case of inflammation, other liver diseases, smoking, and so on. Furthermore, ctDNA has the potential to reflect comprehensive genomic information and overcome intratumor heterogeneity. The current project aims to determine the feasibility of ctDNA detection in small volumes of capillary blood to ensure this promising new biomarker can be implemented in future home-based surveillance strategies for cancer patients. Although this project proposes to use patients with colorectal liver metastases (CRLM) for proof of principle to leverage experiences gained in the MIRACLE and CASA studies, results will be highly relevant for other cancers currently lacking reliable blood-based tumour markers as well. Ultimately this will pave the way for homebased, patient-centred follow up after surgical removal of cancerous lesions irrespective of tumour type, which will reduce the burden on the health care system while improving patient satisfaction.

Study objective

The primary objective of the study is to determine the technical feasibility of ctDNA detection in small volumes of capillary blood. This will be investigated through determining the agreement between ctDNA measurements in venous (standard blood collection) versus capillary blood through automated capillary blood sampling. We will consider a Kappa >0.75 as sufficient agreement.

Study design

This proof-of-concept study aims to determine technical feasibility of ctDNA detection in small volumes of capillary blood in 35 patients. Venous blood from the same patients will be used as reference

Study burden and risks

There is no specific benefit to the participants from participating. Potential

risks associated with participation are low
to mild discomfort and/or temporary superficial hematomas of the skin after venipuncture and use of the TAP device on the upper arm.

The burden on test subjects is minimal. A participating patient will perform one extra blood sample (TAP) under the supervision of a researcher at the outpatient clinic. Furthermore, an extra blood tube will be filled during a standard blood collection at the blood collection station. This will happen at a time when the patient has to go to the blood test anyway for a blood test for the regular treatment process. The time a patient will spent on this study is about 10-15 minutes in total. The current pilot study has the potential to enable future blood collection at home for a much larger group than patients with colon cancer and the results will therefore be more widely applicable.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age >= 21 years
* A history of histologically confirmed (metastatic) colorectal adenocarcinoma
* Currently diagnosed with (progressive) colorectal liver metastases (CRLM)
* Signed informed consent

Exclusion criteria

* Patients who are treated and having a response on preoperative chemotherapy, as this may have an effect on the investigated biomarker load
* Illiteracy and/or insufficient proficiency of the Dutch language
* Known medical history of superficial or deep skin infection after venipuncture or intravenous line that required antibiotic treatment and or hospital admittance
* Known medical history of immunodeficiency or current use of medical immunosuppressants
* Known medical history of blood-borne diseases such as, but not limited to, the human immunodeficiency virus, hepatitis and viral hemorrhagic fever

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):	01-05-2025
Enrollment:	35
Type:	Anticipated

Medical products/devices used

Generic name:	Touch Activated Phlebotomy device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-04-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL88018.078.24
Other	Volgt