Smart measurement of circulating tumor DNA: a tumor-agnostic computational tool to improve colorectal cancer care

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To evaluate the efficacy of a new tumor-agnostic ctDNA assay, the ctDNA estimator, to detect newly developing tumors in Lynch carriers.

Ethical review	Approved WMO
Status	Pending
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON57448

Source
ToetsingOnline

Brief title
the SMART study

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, malignant tumors

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Cancer, Liquid Biopsy, Lynch Syndrome

Outcome measures

Primary outcome

The agreement between estimated ctDNA fractions and the presence of cancer.

Secondary outcome

N.A.

Study description

Background summary

Lynch Syndrome carriers have a predisposition to develop various types of cancer, especially colorectal cancer (CRC) and endometrial cancer (EC). LS patients are advised to undergo surveillance by colonoscopy every 2 year and gynaecological surveillance. This surveillance is deemed burdensome and fails to detect a small part of the developing CRCs and the majority of extra-colonic cancers. To ensure prevention and early detection of cancer, a reliable and accessible test is needed.
Recent studies have shown the potential of the detection of tumor-derived DNA fragments (circulating tumor DNA; ctDNA). Various molecular characteristics can be used to discriminate ctDNA from healthy circulating cell-free DNA. Current ctDNA assays with the highest sensitivity and specificity to detect for example minimal residual disease (MRD) after surgery are mostly tumor-informed, which means prior information is needed from the tumor tissue about the molecular alterations present. As this information is not available for the detection of newly arising tumors, the aim of this study is to evaluate the use of an optimized combination of tumor-agnostic ctDNA characteristics for the detection of newly developing tumors.

Study objective

To evaluate the efficacy of a new tumor-agnostic ctDNA assay, the ctDNA estimator, to detect newly developing tumors in Lynch carriers.

Study design

case-control study

Study burden and risks

Blood will be drawn only once, 3 tubes of 10 mL from LS carriers with a recently diagnosed cancer, which will be combined with a routine hospital visit when possible. The risk of blood collection by venepuncture is negligible

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

(suspect) LS carriers who:
- Have proven Lynch Syndrome (MMR gene or EpCAM mutation);
- Have been diagnosed with any form of cancer at time of inclusion, but have

had treatment yet

Exclusion criteria

(suspect) LS carriers who:
- Are unwilling to undergo extra blood sampling;
- Have no newly diagnosed tumors at time of inclusion;
- Have been treated for their tumor at time of inclusion.

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:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-04-2025
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	NL87476.078.24