Feasibility, reliability, and satisfaction of carcinoembryonic antigen measurements using home based (automated) Capillary bloodsampling; the prospective CASA-I study

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

Summary

ID

NL-OMON52336

Source
ToetsingOnline

Brief title
CASA-I study

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,Labonovum ,Seventh Sense Biosystems

Intervention

Keyword: Capillary sampling, Colorectal cancer, Follow-up, Homebased

Outcome measures

Primary outcome

The primary objective of the study is to determine feasibility of CEA assessments at home using (automated) capillary sampling. Home based (automated) capillary sampling will be considered feasible if a success rate of 85% or greater has been reached. Herein a successful (automated) capillary sampling at home is defined as a sampling of blood by the patient that reached the clinical laboratory of the hospital and in which a CEA level could be determined reliably and that was comparable to the prior measurement sampled by venipuncture.

Secondary outcome

Secondary objectives of the study are to assess reliability and satisfaction of (automated) capillary CEA measurements. Blood samples collected under identical pre-analytical conditions using automated capillary sampling, lancet capillary sampling and venipuncture will be compared on agreement using Bland-Altman analysis 39. Herein the measurement obtained from the venipuncture sample will be considered the golden standard. The mean bias and corresponding 95% limits of agreement of (automated) capillary samples and the golden standard will be calculated. A mean bias of +/- 5% or greater and 95% limits of agreement of

greater than +/- 10% will be considered clinically relevant and thereby unreliable.

Satisfaction of (automated) capillary sampling will be evaluated in terms of patient reported outcome measures on pain, burden, ease of use, and preference. Perceived levels of pain measured on a visual analogue scale (VAS) will be compared across automated capillary sampling, lancet capillary sampling, and venipuncture. It is hypothesized that automated capillary sampling will be perceived as least painful, least burdensome, most easy to use, and will be the preferred method of blood sampling for the majority of study subjects.

Finally, the clinical laboratory sample processing time will be compared across automated capillary sampling, lancet capillary sampling, and venipuncture.

Study description

Background summary

The follow-up of patients after colorectal cancer surgery mainly consists of blood CEA assessments. These blood assessments could be done at home and could be beneficial in terms of patients* well-being and societal cost-effectiveness Traditional blood sampling by venipuncture is rather unsuitable for home based sampling due to associated pain and its dependency on medical personnel. Furthermore, excessive fear of needles is an often neglected aspect of venipuncture, as it affects at least 10% of the population. To truly enable home based CEA assessments, evaluation of novel blood sampling techniques that are associated with less pain, that do not require the use of needles and that can be performed independent of medical personnel are necessitated. Capillary blood sampling can be an alternative to venipuncture in home based or decentralized surveillance as it can be performed by the patient themselves. Traditional capillary sampling is done by using a lancet to puncture the skin of a finger. The resulting skin defect allows for blood sampling by repeatedly

applying pressure to the finger. This generates droplets of blood at the barrier defect which can be collected one by one in a small capillary blood tube. Although lancet capillary sampling will likely allow successful sampling at home, some drawbacks still remain. The procedure involves multiple steps that require some degree of fine motor skill and involves inflicting a small amount of pain on oneself.
Recently new capillary sampling devices have been developed that automate the sampling, collection and storage of capillary blood into a single painless action. Such novel devices would be ideal for blood sampling in decentralized surveillance strategies. Home based sampling could also be implemented in centralized surveillance. It could reduce the number of hospital visitations, as blood sampling and consultations are often separate visits. Before home based capillary sampling can be implemented, feasibility, reliability, and satisfaction for serum CEA measurements has to be determined.

Study objective

The primary objective of the study is to determine feasibility of CEA assessments at home using (automated) capillary sampling. Home based (automated) capillary sampling will be considered feasible if a success rate of 85% or greater has been reached. Herein a successful (automated) capillary sampling at home is defined as a sampling of blood by the patient that reached the clinical laboratory of the hospital and in which a CEA level could be determined reliably and that was comparable to the prior measurement sampled by venipuncture.

Study design

The study is a prospective cohort study of 100 subjects to determine feasibility, reliability, and satisfaction of (automated) capillary sampling compared to venipuncture. To properly determine reliability of (automated) capillary CEA measurements, elevated, normal, and low CEA levels need to be evaluated under identical pre-analytical circumstances. A three armed approach is therefore taken:
Arm A: 20 subjects with known elevated serum CEA (elevated levels)
Arm B: 60 subjects currently undergoing CRC related follow-up (normal levels)
Arm C: 20 volunteers with no known history of CRC (low levels)

Reliability of CEA measurements will be assessed for automated capillary and lancet capillary sampling compared to venipuncture across all three arms. Satisfaction in terms of patient reported outcomes (pain, burden, ease of use, and preference) will be evaluated in all 100 study subjects. Feasibility of capillary sampling at home will be assessed in Arm B only: 60 patients undergoing CRC related follow-up. Patients in Arm B will be asked to perform automated capillary sampling and lancet capillary sampling at home twice after regular check-up visits in the hospital, with an interval of 3-6 months in

between. During this hospital visit, a CEA measurement in blood sampled by venipuncture will be performed to act as a reference for the CEA measurements in (automated) capillary blood to be sampled at home. A schematic overview of the study design is provided in appendix A.

Study burden and risks

All study subjects will be asked to report on their perceived pain, burden, ease of use, and preference of the techniques by completing a questionnaire. In addition, patients who currently undergo CRC related follow-up will be asked to complete automated and lancet capillary sampling at home after two regular hospital visitations, after which they will complete the questionnaire for a second time. There is no specific benefit associated with participation for the study subjects. Potential risks associated with participation are low to mild discomfort and/or temporary superficial hematomas of the skin following venipuncture. For the volunteers in study arm C a potential risk will be determination of an elevated CEA, after which subjects may be subjected to other diagnostics studies to diagnose or rule out a CRC (related) cause of elevated blood CEA.

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

Group A:
Age >= 21 years
Histologically confirmed (metastatic) colorectal adenocarcinoma
Serum CEA >= 10 µg/L within the last 2 months determined using venipuncture blood sampling

Group B:
Age >= 21 years
Histologically confirmed (metastatic) colorectal adenocarcinoma
Currently undergoing in-hospital follow-up with at least two more scheduled serum CEA assessments 3-6 months apart

Group C:
Age >= 21 years
No known history of colorectal adenocarcinoma
No known history of elevated serum CEA >= 5 µg/L

Exclusion criteria

Illiteracy and/or insufficient proficiency of the Dutch language
Severe or complete loss of sensory and or motor function of one or both arms and or hands
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:	Recruitment stopped
Start date (anticipated):	25-03-2022
Enrollment:	100
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	20-01-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	31-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	30-09-2022
Application type:	Amendment
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
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL78309.078.21