Detecting cancers Earlier Through Elective plasma-based CancerSEEK Testing - Ascertaining Serial Cancer patients to Enable New Diagnostic II (DETECT-ASCEND 2)

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The primary objective of this study is to obtain clinically characterized, whole blood specimens from subjects with a new or suspected diagnosis of cancer (cancer subjects) and from subjects who do not have a diagnosis of cancer (healthy) to develop...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56411

Source
ToetsingOnline

Brief title
DETECT ASCEND 2

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
early detection of cancer - blood test

Health condition

single blood draw for early detect of cancer

Research involving
Human

Sponsors and support

Primary sponsor: Exact Sciences Thrive LLC
Source(s) of monetary or material Support: Medical device industry

Intervention

Keyword: Blood, CancerSeek, Early detecting cancer

Outcome measures

Primary outcome

The purpose of this study is to obtain clinically characterized, whole blood

specimens from cancer subjects and healthy subjects to develop and refine

assays for cancer in the blood.

Secondary outcome

N/A

Study description

Background summary

Cancer is the second leading cause of death in the United States, with an estimated 600,000 people expected to die from the disease this year. Most of these cancers are often detected too late, and only after people start to experience symptoms. These *symptom-detected* cancers too frequently coincide with late stage, metastatic disease, and result in poor outcomes. However, when cancer is detected through screening, or are *screen-detected,* the disease is often identified earlier when it can be more effectively treated, and in many cases even cured.

CancerSEEK is a blood test designed to detect multiple types of cancer at the earliest stages possible. The CancerSEEK test has been shown in both retrospective and prospective settings to be able to detect many different types of cancer for which routine,
SOC screening modalities are not presently available.

CancerSEEK as a minimally invasive multi cancer screening test, employed in a complementary fashion with currently approved SOC cancer screening approaches may be able to increase cancer detection rates.

Study objective

The primary objective of this study is to obtain clinically characterized, whole blood specimens from subjects with a new or suspected diagnosis of cancer (cancer subjects) and from subjects who do not have a diagnosis of cancer (healthy) to develop and refine assays for cancer in the blood.

Study design

This is a prospective study of cancer and healthy subjects that will be conducted in the United States and parts of Europe (Germany, Hungary, France, United Kingdom, and the Netherlands). Enrollment of approximately 32,000 subjects overall is anticipated with approximately 8,000 stage I-IV cancer subjects and approximately 24,000 healthy subjects. Enrollment into the study will occur after eligibility is confirmed and informed consent obtained. Once informed consent is obtained, subject data will be collected and subjects will undergo an approximate 51mL blood draw, at which time their participation in the study will be considered complete. Blood will be packaged and sent to a central laboratory for processing and analyses per sample collection and shipping instructions provided by the Sponsor.

Study burden and risks

Subjects will undergo 1 blood draw.
Risk from blood draw is minimal. During or after bloods draws, subject may have pain, swelling, or bruising where the needle enters the vein. There may be risk of infection. Subject may feel dizzy or faint.
As there are no benefits to subjects enrolled in this study. Participation will help in the search for improved cancer diagnosis which may benefit future cancer patients.

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

All subjects
1. >=50 years of age
2. Subject understands the study procedures and is able to provide informed consent to participate in the study and authorization for release of relevant protected health information to the study investigator.
Cancer Subjects Only
3. Subject has an untreated primary malignancy of breast, lung, colorectal, prostate, bladder, uterine, kidney/renal pelvis, pancreatic, liver, stomach, ovarian, esophageal cancer, head and neck squamous cell, thyroid, small intestine, cervical, anal, vulva, or testis confirmed through pathology reports and/or clinical/radiographic data.
Or
4. Subject has suspicion of a primary malignancy of pancreatic, bladder, kidney/renal pelvis, testis or ovarian cancer based on imaging.

Exclusion criteria

1. Prior or concurrent cancer diagnosis defined as:

a. Any previous cancer diagnosis within the past 5 years (with the exceptions of basal cell or squamous cell skin cancers); OR
b. Recurrence of the same primary cancer within any timeframe; OR
c. Concurrent diagnosis of multiple primary cancers
2. Chemotherapy and/or radiation therapy within 5 years prior to enrollment/sample collection.
3. Any treatment for the primary malignancy or sites of metastases. Subject may not have started neo-adjuvant chemotherapy, neo-adjuvant radiation therapy, immunotherapy or other treatment and/or surgery prior to blood sample collection.
4. Less than 3 days between fine needle aspiration (FNA) of target pathology and blood collection.
5. Less than 7 days between biopsy (other than FNA) of target pathology and blood collection.
6. IV contrast (e.g., CT and MRI) within 1 day [or 24 hours] prior to blood collection.
7. Individual has a condition the Investigator believes would interfere with the subject*s ability to provide informed consent, comply with the study protocol, which might confound the interpretation of the study results or put the person at undue risk.
8. Participant has an active febrile infection prior to blood draw
9. History of an allogeneic bone marrow, stem cell transplant, or solid organ transplant

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-12-2022
Enrollment:	294

Type:	Actual

Ethics review

Approved WMO Date:	06-12-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-10-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80557.091.22