CELTiC trial: an international multicentre study evaluating the CELTiC panel for the detection of advanced neoplasia in Feacal Immunochemical Test (FIT)-positive individuals

Published: 11-06-2021
Last updated: 05-04-2024

We aim to estimate the sensitivity and specificity of the CELTiC panel in FIT-positive populations.

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

Summary

ID

NL-OMON50791

Source
ToetsingOnline

Brief title
CELTiC trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Advanced neoplasia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Celtic Medical

Intervention

Keyword: Advanced Neoplasia, CELTiC, Colorectal Cancer, Diagnosis

Outcome measures

Primary outcome

Primary: sensitivity of the CELTiC panel for detecting advanced neoplasia at a threshold with an expected sensitivity of 90%;

Secondary outcome

Secondary: specificity and positive predictive value of the CELTiC panel for detecting advanced neoplasia at a threshold with an expected sensitivity of 90%; specificity and positive predictive value of the CELTiC panel for detecting advanced neoplasia at a threshold with an observed sensitivity of 90%; C-statistic of the CELTiC panel; association between CELTiC score and FIT concentration.

Study description

Background summary

Colorectal Cancer (CRC) is one of the leading causes of cancer in developed regions around the world and its incidence is rising. Many nations or regions have introduced CRC population screening programmes to detect cancerous lesions before symptoms arise or to detect precursor lesions whose eradication may prevent CRC.

The Faecal Immunochemical Test (FIT) is used to screen for CRC in many nations and regions around the world. Its advantages include ease of use, the ability to be performed at home and to be sent by mail to a laboratory, and its

cost-efficiency. Moreover, these characteristics enable population-wide screening without the need for all participants to undergo a colonoscopy.

However, a downside of the FIT is its performance. In the Netherlands, where a FIT cut-off concentration of 47 mcg Hb/g faeces is used, the FIT produces a negative result in 15% of people who have CRC. For the detection of CRC and Advanced Adenomas (AA), referred to as Advanced Neoplasia (AN), the FIT falsely provides a negative result in up to 70% of people with AN. In addition, more than half of the people with a positive FIT result in the Netherlands do not have any (pre)cancerous lesions at colonoscopy.

One way to improve the efficiency of CRC screening is to introduce a second test to FIT-positive screening participants, to further select individuals for a colonoscopy. Ideally, this test should have a high sensitivity since a false negative result would lead to denying a colonoscopy to a FIT-positive individual with a (pre)cancerous lesion. In addition, the specificity of this test should be high enough to substantially reduce the number of FIT-positive individuals without AN undergoing colonoscopy.

The CELTiC panel is a blood-based test comprising of four mRNA markers (LGALS4, CEACAM6, TSPAN8, and COL1A2). In a sample of 128 individuals the panel reached an AUC of 0.82 in discriminating individuals with AN (n = 92; AA n = 25, CRC n = 67) from individuals with a positive FIT result but a normal colonoscopy (n = 36). The CELTiC panel could potentially function as a second test for individuals with a positive FIT result and reduce the number of unnecessary colonoscopies7. Furthermore, by simultaneously lowering the cut-off concentration of the FIT and introducing the CELTiC panel, screening programs may potentially detect more individuals with AN without increasing the number of colonoscopies performed.

This will be the first study prospectively investigating the CELTiC panel in a large cohort sourced exclusively from the target population. We therefore believe this study will add important knowledge on the accuracy of the CELTiC panel in a realistic clinical setting.

Study objective

We aim to estimate the sensitivity and specificity of the CELTiC panel in FIT-positive populations.

Study design

We designed an international multicentre cross-sectional and observational study in two separate screening populations (Italy and the Netherlands)

Study burden and risks

If blood sampling through a peripheral venous catheter fails, we will draw a blood sample through venepuncture. This procedure may cause pain and discomfort, albeit tolerably and temporary.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Individuals with a positive FIT test in the national CRC screening program of the Netherlands and Italy, between 55 and 75 years old (Netherlands), or 50 and 69 years old (Italy).

Exclusion criteria

Individuals with Inflammatory Bowel Disease, under current treatment of colorectal cancer, or under current endoscopic surveillance.

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):	03-08-2021
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO Date:	11-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL77730.018.21