# The prospective data collection initiative on on small bowel, colorectal and anal cancer - a prospective observational cohort study.

Published: 06-02-2014
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The main objectives of this project are:- To start a prospective observational cohort study of patients who have been diagnosed with CRC, small bowel and anal cancer and follow them from time of diagnosis until death.- To prospectively collect data…

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment started |
| **Health condition type** | Gastrointestinal neoplasms malignant and unspecified |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON54603

**Source**
ToetsingOnline

**Brief title**
PLCRC

### Condition

- Gastrointestinal neoplasms malignant and unspecified

**Synonym**
anal cancer Colorectal Cancer small bowel cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Dutch Colorectal Cancer Group

**Source(s) of monetary or material Support:** PGDX,Servier,Pierre Fabre,KWF,Dutch Colorectal Cancer Group,Stichting voor Lever- en Maag-Darm Onderzoek,Nutricia,Hoffmann-La Roche,Bayer,Eli Lilly

## Intervention

- Other intervention

**Keyword:** Anal cancer, Cohort, Colorectal cancer, Prospective

**Explanation**

N.a.

## Outcome measures

**Primary outcome**

1. Clinical parameters: medical history, co-morbidity, medication use, basic<br />
physical examination, laboratory results, imaging results, pathology results,<br />
tumor characteristics, treatment, treatment outcomes, hospital stays,<br />
interventions and adverse events.<br />
2. Clinical endpoints: treatment effect, adenoma-free survival, disease-free<br />
survival, progression-free survival, overall survival and grade 3/4 (serious)<br />
adverse events.<br />
3. Patient reported outcomes: health related quality of life, work<br />
participation and work ability.<br />
4. Biobanking of blood and tumor tissue

**Secondary outcome**

nvt

# Study description

**Background summary**

Survival after cancer diagnosis strongly depends on local tumor extent, lymph node involvement and the presence of distant metastases. However, there remains great inter-patient variability regarding treatment outcome. A combination of biochemical factors, histopathological features, genomic profile, environmental factors and other clinical factors are likely to influence prognosis and treatment effect, independent from tumor stage, but it is still unclear which, how, and to what extent these factors can influence tumor recurrence and

mortality in both early stage (I-III) and late stage (IV) colorectal cancer (CRC), small bowel cancer and anal cancer.
Although the results from prospective clinical trials will remain the backbone of evidence-based medicine, this concerns a highly selected patient population since the large majority (85%-95%) of cancer patients do not participate to clinical trials for various reasons. It is unlikely that trial participation will significantly improve in the near future. This fact has the following implications: 1) It is highly desirable to validate the results from trials in the general patient population. However, this is complicated by the fact that the documentation of patients treated in general practice (i.e. outside the scope of clinical trials) is largely insufficient to provide comparable patient cohorts in terms of prognostic characteristics and treatment parameters. 2) There is an increased availability of novel technologies that provide molecular markers with potential prognostic and/or predictive value. To test the clinical value of these markers large numbers of patients are required which greatly exceeds the number of patients who consent to participate to prospective clinical trials. 3) as a result of rapid technical developments, a range of new minimally invasive treatment options are entering the market. These interventions have the potential to be of great benefit to patients in terms of improved local control, higher probability of complete tumor removal, less damage to surrounding tissue, faster recovery and less short and long term side effects. Still,the interventions will have to prove their effectiveness, safety and superiority (or non inferiority) to standard cancer treatments on a patient level.
A prospective observational cohort study has the great opportunity to fill this gap.
We here propose to initiate such a study in patients with CRC, small bowel cancer and anal cancer in the Netherlands. If successful, it is expected that this study will be adopted to other tumor types as well..

**Study objective**

The main objectives of this project are:

- To start a prospective observational cohort study of patients who have been diagnosed with CRC, small bowel and anal cancer and follow them from time of diagnosis until death.

- To prospectively collect data on medical history, serious comorbidities, basic physical examination, imaging results, pathology results, tumor characteristics, treatment, treatment outcomes, hospital stays, interventions and adverse events.

- To store tumor tissue material, obtained during routine practice, for future research and to collect and store blood samples for observational and future reseach.

- To provide more accurate data on the treatment and clinical/ patient reported outcomes of CRC, small bowel and anal cancer in normal daily clinical care. To create a continuous basis for a large variety of research purposes including:

A. Prognostic and predictive research
B. Biological research and (epi)genetic research
C. Studies that compare new therapies in a target population according to the Trials within Cohorts (TwiCs) design.
D. Health care policies and cost-effectiveness studies

### Study design

prospective observational cohort study

### Intervention

nvt

### Study burden and risks

Since this is an observational study there are no additional risks associated with participation. Clinical (outcome) parameters will be collected during routine care and derived from medical charts. Consenting patients will be asked to fill out standard questionnaires.
If a patient gives informed consent to be approached for possible future studies within this project, he/she can be invited to participate in one or more studies within this project. Patients who consent to participate in the TwiCs part of the project will be informed that their data will be used for comparative evaluation of safety and effectiveness of new interventions. They are also informed about the possibility that they may be offered an experimental intervention, which they may refuse. They are also informed about the fact that if they are not selected for a certain experimental intervention, and therefore are part of the control arm, they may be (temporarily) ineligible for some future experimental interventions.
In any instance, patients will never be withheld from standard, evidence-based treatments.

## Contacts

**Scientific**
Universitair Medisch Centrum Utrecht
A.J.S. van Tetering
Heidelberglaan 100
Utrecht 3584 CX

Netherlands
0646919566
**Public**
Universitair Medisch Centrum Utrecht
A.J.S. van Tetering
Heidelberglaan 100
Utrecht 3584 CX
Netherlands
0646919566

# Trial sites

## Trial sites in the Netherlands

Rivierenland Ziekenhuis
Target size: 114

Universitair Medisch Centrum Utrecht
Target size: 116

Amsterdam UMC
Target size: 111

Elisabeth-Tweesteden ziekenhuis
Target size: 350

Ikazia Ziekenhuis
Target size: 150

Fransiscus Gasthuis & Vlietland
Target size: 300

Scheper Ziekenhuis
Target size: 140

OLVG
Target size: 350

Catharina-ziekenhuis
Target size: 200

Haaglanden Medisch Centrum
Target size: 150

Antonius Ziekenhuis
Target size: 150

Amphia Ziekenhuis
Target size: 300

Admiraal de Ruyter Ziekenhuis
Target size: 225

St. Jans Gasthuis
Target size: 75

Universitair Medisch Centrum Groningen
Target size: 120

MC Groep
Target size: 75

Groene Hart Ziekenhuis
Target size: 150

Alrijne Ziekenhuis
Target size: 175

Sint Annaziekenhuis
Target size: 100

Rivas Zorggroep
Target size: 100

Gelre Ziekenhuizen
Target size: 250

De Heel - Zaans Medisch Centrum
Target size: 300

Diakonessenhuis Utrecht
Target size: 114

Deventer Ziekenhuis
Target size: 200

Zuyderland
Target size: 250

Flevoziekenhuis
Target size: 400

Spaarne Gasthuis
Target size: 350

IJssellandziekenhuis
Target size: 200

Bethesda Ziekenhuis
Target size: 100

Refaja Ziekenhuis
Target size: 100

Isala
Target size: 300

Maastricht Universitair Medisch Centrum +
Target size: 200

Saxenburgh groep

Target size: 100

NKI-AVL
Target size: 50

Maasstadziekenhuis
Target size: 150

Rode Kruis Ziekenhuis
Target size: 125

Reinier de Graaf Groep
Target size: 200

Ziekenhuisgroep Twente
Target size: 300

HagaZiekenhuis
Target size: 200

Medisch Spectrum Twente
Target size: 275

Noordwest Ziekenhuisgroep
Target size: 325

Vrije Universiteit Medisch Centrum
Target size: 50

Bravis Ziekenhuis
Target size: 100

Dijklander Ziekenhuis
Target size: 200

Martini Ziekenhuis
Target size: 350

Elkerliek Ziekenhuis
Target size: 100

Canisius Wilhelmina Ziekenhuis
Target size: 200

Ziekenhuis Amstelland
Target size: 250

Slingeland Ziekenhuis
Target size: 300

Maasziekenhuis
Target size: 300

Ziekenhuis Tjongerschans
Target size: 300

St. Antonius Ziekenhuis
Target size: 114

Meander Medisch Centrum
Target size: 114

Zuwe Hofpoortziekenhuis Woerden
Target size: 114

Tergooi ziekenhuizen
Target size: 114

Erasmus Medisch Centrum
Target size: 75

Leids Universitair Medisch Centrum
Target size: 120

Radboud Universitair Medisch Centrum
Target size: 100

Albert Schweitzer Ziekenhuis
Target size: 275

MAASTRO clinic
Target size: 250

Bernhoven
Target size: 200

Medisch Centrum Leeuwarden (MCL)
Target size: 250

Viecuri Medisch Centrum voor Noord-Limburg
Target size: 250

Wilhelmina Ziekenhuis
Target size: 125

Rijnstate Ziekenhuis
Target size: 250

Zorgsaam ziekenhuis
Target size: 100

Laurentius ziekenhuis
Target size: 100

Jeroen Bosch Ziekenhuis
Target size: 200

Maxima Medisch Centrum
Target size: 175

Van Weel-Bethesda Ziekenhuis
Target size: 90

Ziekenhuis St Jansdal
Target size: 125

Medisch Centrum de Veluwe

Target size: 50

Ziekenhuisvoorzieningen Gelderse Vallei
Target size: 225

Sint Annaziekenhuis
Target size: 300

Nij Smellinghe Ziekenhuis
Target size: 500

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

Age of 18 years or older
Histological proof of colorectal, small bowel or anal cancer, or a strong suspicion after imaging
Informed consent for longitudinal observational data collection

### Exclusion criteria

Mentally incompetent

## Study design

### Design

Study phase: N/A

Study type: Observational non invasive

Intervention model: Single

Allocation: Non controlled trial

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment started |
| Start date (anticipated): | 08-07-2014 |
| Enrollment: | 100000 |
| Duration: | 60 months (per patient) |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | N.a. |

### IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
N.a.

## Ethics review

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|---|---|
| Approved WMO Date: | 18-06-2014 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 27-10-2014 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 20-04-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |

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|---|---|
| Date: | 21-04-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 04-06-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 05-08-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 17-08-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 19-08-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 19-10-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 02-12-2015 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 28-01-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 10-03-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |

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|---|---|
| Date: | 23-03-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 18-04-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 29-07-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 07-09-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 16-09-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 21-09-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 05-10-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 12-10-2016 |
| Application type: | Amendment |
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| Approved WMO Date: | 19-10-2016 |
| Application type: | Amendment |
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| Date: | 26-10-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 09-11-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 30-11-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 07-12-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 20-12-2016 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 06-02-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 09-03-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 29-03-2017 |
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| Date: | 03-04-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 05-04-2017 |
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| Approved WMO Date: | 13-04-2017 |
| Application type: | Amendment |
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| Approved WMO Date: | 19-04-2017 |
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| Approved WMO Date: | 25-04-2017 |
| Application type: | Amendment |
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| Approved WMO Date: | 26-04-2017 |
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| Date: | 01-08-2017 |
| Application type: | Amendment |
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| Approved WMO Date: | 04-10-2017 |
| Application type: | Amendment |
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| Approved WMO Date: | 25-10-2017 |
| Application type: | Amendment |
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| Approved WMO Date: | 15-11-2017 |
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| Approved WMO Date: | 16-11-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 22-11-2017 |
| Application type: | Amendment |
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| Date: | 17-01-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 24-01-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 01-02-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 06-03-2018 |
| Application type: | Amendment |
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| Approved WMO Date: | 03-09-2024 |
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| | |
|---|---|
| Date: | 01-04-2025 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

# 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 | 12-510 |
| CCMO | NL47888.041.14 |
| Research portal | NL-008405 |