

# Glycaemic control in patients with type 2 diabetes and colorectal- or breast cancer treated with curative intent

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON23282

### Source

NTR

### Brief title

-

### Health condition

Type 2 diabetes (T2DM)  
Breast cancer/borstkanker  
Colorectal cancer/colorectale kanker  
Hypertension/hypertensie  
Dyslipidemia/dyslipidemie

## Sponsors and support

**Primary sponsor:** Diabetes Kenniscentrum Zwolle

**Source(s) of monetary or material Support:** the Netherlands Organisation for Health Research and Development (ZonMW)

## Intervention

## Outcome measures

### Primary outcome

The proportion of patients who achieve their individual treatment goal at 0, 12 months and 24 months after cancer diagnosis and treatment compared to baseline.

### Secondary outcome

The proportion of patients who achieve a target cholesterol/HDL ratio equal or below 4 at 0, 12 and 24 months compared to baseline.

The proportion of patients who achieve a target systolic blood pressure equal to or below of 140 mmHg at 0, 12 and 24 months compared to baseline.

## Study description

### Background summary

This pilot study is part of a prospective cohort study, using data from the Zwolle Outpatient Diabetes project Integrating Available Care (ZODIAC) cohort and data concerning cancer from the Dutch Cancer Registry (NKR). Little is known about glycaemic control in patients who have received cancer treatment with curative intent. The aim of this project is to investigate the quality of diabetes care of type 2 diabetes patients with breast or colorectal cancer compared to those without cancer.

Patients participating in this study are diagnosed with T2DM and are treated in primary care in the Netherlands. In addition, they are diagnosed with primary breast- or colorectal cancer. For this study information about HbA1c, cholesterol/HDL ratio, blood pressure, diabetic medication use and cancer treatment were collected.

### Study objective

We hypothesize that the quality of diabetes treatment, measured as glycaemic control, is worse in patients with T2DM and colorectal- and breast cancer treated with curative intent, compared to T2DM patients without cancer, at 1 and 2 years after cancer treatment.

### Study design

The follow-up time will start at 1 year before cancer diagnosis (baseline) and the primary and secondary outcomes will be analysed at 0, 12 and 24 months after cancer diagnosis.

### Intervention

## Contacts

### Public

Dr. Spanjaardweg 11, 2e etage

Dennis Schrijnders  
Zwolle 8025 BT  
The Netherlands  
0031-38-4247763

### Scientific

Dr. Spanjaardweg 11, 2e etage

Dennis Schrijnders  
Zwolle 8025 BT  
The Netherlands  
0031-38-4247763

## Eligibility criteria

### Inclusion criteria

Patients with type 2 diabetes treated in primary care, who are diagnosed with primary breast- or colorectal cancer, between 1999 and 2012 and who are treated with curative intent. Curative intent for breast cancer was defined as stage 1 to 3 breast cancer or ductal carcinoma in situ (DCIS) of the breast. Curative intent for colorectal cancer was defined as stage 1 to 3, who received at least surgical treatment.

### Exclusion criteria

Patients with evidence of relapse, patients with other cancers than breast or colorectal cancer, or patients with a history of other cancers prior to breast or colorectal cancer with the exception for non-melanoma skin cancer and patients who received no cancer treatment or only hormone treatment in breast cancer are excluded. Patients without at least 1 year of follow-up in the ZODIAC study prior to the diagnosis of breast or colorectal cancer are also excluded.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	156
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	15-01-2016
Application type:	First submission

## 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

NTR-new

NTR-old

Other

### ID

NL5533

NTR5652

13.0765 : METC

## Study results

### Summary results

-