# Adherence and patients’ experiences with capecitabine.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON21382

**Source**
Nationaal Trial Register

**Brief title**
Caper

**Health condition**

Colorectal cancer, gastric cancer and breast cancer.

### Sponsors and support

**Primary sponsor:** VU University Medical Center
**Source(s) of monetary or material Support:** Roche Nederland BV

### Intervention

### Outcome measures

**Primary outcome**

Adherence rate: A patient is adherent with the intake of 85% or more of the prescribed medication.

**Secondary outcome**

1. Number and grade of side-effects;

2. Attitude towards disease;

3. Beliefs and attitude towards medicines.

# Study description

**Background summary**

Background of the study:

Adherence to treatment is a complex and multifaceted issue that can substantially alter the outcomes of therapy. Variation in plasma concentration may be due to variability in pharmacokinetics. Even in a clinical trial setting there is a considerable variability in efficacy and side effects of capecitabine. In a less controlled environment, like the use of capecitabine in daily practice, adherence may also play a significant role. Only few studies have focused on the use of oral anticancer drugs in daily practice and the influence of adherence to its effectiveness. Information about the reasons for non-adherence among cancer patients taking the oral anticancer drug capecitabine is essential for the development of interventions that may increase adherence.

Objectives of the study:

Primary objective: Adherence in patients starting the use of capecitabine and the influence of patients attitudes and side effects on adherence.

Secondary objective: The second part of this study contains 1) a validation study of the adherence measurements and 2) an explorative study. The relationships between the following parameters will be explored: Patient characteristics, disease characteristics, side effects, quality of life, patients beliefs and attitude towards disease and medicines, satisfaction with information, adherence, dose adjustments and plasma concentration of 5'-DFUR, 5-FU and FBAL in patients with cancer will be studied.

Study design/methods:

Prospective observational cohort study in which 66 patients starting with treatment with capecitabine will be followed up until five cycles of three weeks. Cancer patients of 18 years or older under treatment in one of the participating hospitals in the Netherlands starting with capecitabine can be included. Before the start of therapy with capecitabine and during the

second week of cycle 1, 3 and 5 patients will be asked to fill in a questionnaire. Before the start of therapy with capecitabine baseline blood samples are collected. Furthermore in the second week of cycle 1, 3 and 5 blood samples are collected, which will be analysed for plasma concentration of 5'-DFUR, 5-FU and FBAL.

### Study objective

The present study aims to get more insight into the various aspects that govern adherence to the oral anticancer drug capecitabine in daily practice.

### Study design

Baseline and during the second week of cycle 1, 3 and 5.

### Intervention

The use of capecitabine in daily practice will be monitored for 5 cycles. Every cycle takes three weeks.

## Contacts

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## Eligibility criteria

### Inclusion criteria

Cancer patients starting with capecitabine.

### Exclusion criteria

Younger than 18 years of age or insufficient knowledge of the Dutch language.

## Study design

### Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |

**Control:** N/A , unknown

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-02-2010 |
| Enrollment: | 66 |
| Type: | Actual |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 11-05-2010 |
| 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 | ID |
|---|---|
| NTR-new | NL2200 |
| NTR-old | NTR2324 |
| Other | VUmc, KFA : OZ05KFA00000 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A