Adherence and patients' experiences with the use of capecitabine in cancer treatment: The exploration of factors affecting the use in daily practice

Published: 08-12-2009
Last updated: 06-05-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON36444

Source
ToetsingOnline

Brief title
Adherence and patients* experiences with capecitabine

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal cancer, gastric cancer and breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Roche Nederland B.V.

Intervention

Keyword: Adherence, Capecitabine, Daily practice, Oral chemotherapy

Outcome measures

Primary outcome

Adherence rate; a patient is adherent with the intake of 85% or more of the

prescribed medication.

Secondary outcome

Number and grade of side-effects according to patients experience

Attitude towards disease

Beliefs and attitude towards medicines

Study description

Background summary

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.

Study objective

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

Prospective observational cohort study in which 90 patients starting with treatment with capecitabine will be followed up until five cycles of three weeks.

Study burden and risks

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.

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

Cancer patients starting with capecitabine

Exclusion criteria

younger than 18 year

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2010
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	08-12-2009
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-04-2011
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	NL28334.029.09