Adherence and patients’ experiences with capecitabine.

Gepubliceerd: 11-05-2010 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21382

Bron
Nationaal Trial Register

Verkorte titel
Caper

Aandoening

Colorectal cancer, gastric cancer and breast cancer.

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: Roche Nederland BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Cancer patients starting with capecitabine.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-02-2010
Aantal proefpersonen:	66
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-05-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2200
NTR-old	NTR2324
Ander register	VUmc, KFA : OZ05KFA00000
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A