Adherence and patients’ experiences with oral anticancer agents.

Gepubliceerd: 10-05-2011 Laatst bijgewerkt: 13-12-2022

The present study aims to get more insight into the use of oral anticancer agents in daily practice.

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

Samenvatting

ID

NL-OMON21194

Bron
NTR

Aandoening

cancer

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: In progress

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Adherence rate.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Cytotoxic therapies given IV have always been the most important drugs for treatment of cancer. However, in the past decade both the availability and use of oral anticancer agents have increased. Suboptimal adherence to oral (cancer)therapies can have multiple consequences. Only few studies have focused on the use of oral anticancer agents in daily practice and the factors governing adherence. Information about the reasons for non-adherence among cancer patients taking oral anticancer agents is essential for the development of interventions that may increase adherence and positively alter therapy outcomes.

Objectives:

Primary: Determination of the adherence in patients using an oral anticancer agent.

Secondary: Determination of the influence of side effects and patients' attitudes towards disease and medication on adherence and other factors that may influence adherence to oral anticancer agents in daily practice.

Method:

Observational multicenter study in which patients who filled a prescription for an oral anticancer agent in the past period of three months, will be extracted from the pharmacy databases and inquired for participation. The following drugs will be included: lenalidomide, thalidomide, dasatinib, imatinib, nilotinib, erlotinib, gefitinib, sorafenib, sunitinib, everolimus, capecitabine, lapatinib, temozolomide. Patients will be asked to sign informed consent.

Adherence rate will be determined using the Patient's files-Pharmacy records-Pill count method (PPP-method): Patients will be contacted by the researcher by phone to count their remaining pills at that moment. The pharmacy records and data on drug prescription in the medical file of the patient will be assessed. Patients will be asked whether they had returned pills at the pharmacy or disposed pills at any other way. The actual used number of tablets will be calculated from this obtained information (dispensions minus pill count) and compared to the prescribed number of tablets, as registered in the patient's medical file.

Data of the prescribed dose, dose adjustment and information concerning the disease will be

retrieved from the patient’s medical file.

Data of patient and treatment related factors will be collected by means of two questionnaires. These factors include date of birth, gender, partner status, socio-economic status, adherence by means of Medication Adherence Rating Scale (MARS), nature and grade of side effects as perceived by the patient, quality of life (EORTC QLQ-C30), attitude towards disease (Brief IPQ) and medication (BMQ), the information received about the medication (SIMS), and discontinuation.

Doel van het onderzoek

The present study aims to get more insight into the use of oral anticancer agents in daily practice.

Onderzoeksopzet

Patients are contacted ones by phone. The two questionnaires will be send afterwards.

Onderzoeksproduct en/of interventie

Adherence will be determined using the Patient’s files-Pharmacy records-Pill count method (using data of the patient’s medical file, pharmacy dispensions, and a pill count). Patients are asked to fill out two questionnaires.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with cancer of 18 years and older who have filled at least one prescription for an oral anticancer agent in the past period of three months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients younger than 18 years;

2. Treatment in the (neo)adjuvant setting;

3. Not eligible according to the doctor;

4. Unable to fill out questionnaires;

5. Insufficient knowledge of the Dutch language;

6. No signed informed consent.

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:	10-11-2010

Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-05-2011
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	NL2752
NTR-old	NTR2891
Ander register	METC VUmc : 2010/277
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A