Adherence and patients’ experiences with oral anticancer agents.

No registrations found.

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

Summary

ID

NL-OMON21194

Source
NTR

Health condition

cancer

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: In progress

Intervention

Outcome measures

Primary outcome

Adherence rate.

Secondary outcome

1. Nature and grade of side effects as perceived by the patient;

2. Attitude towards disease;

3. Beliefs and attitude towards medication;

4. Information received about the medication;

5. Quality of life;

6. Adherence by means of Medication Adherence Rating Scale (MARS);

7. Dose adjustment;

8. Discontinuation;

9. Age;

10. Gender;

11. Partner status;

12. Socio-economic status;

13. Disease stage.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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.

Contacts

Public
L. Timmers
Universitaire Poliklinische Apotheek VUmc,
De Boelelaan 1118, PK 0 hal 54
Amsterdam 1081 HZ
The Netherlands
+31 (0)20 4442777
Scientific
L. Timmers
Universitaire Poliklinische Apotheek VUmc,
De Boelelaan 1118, PK 0 hal 54
Amsterdam 1081 HZ
The Netherlands
+31 (0)20 4442777

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

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):	10-11-2010
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

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

Study results

Summary results
N/A