Drug interactions and duplicate prescriptions among ambulatory cancer patients.

No registrations found.

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

Summary

ID

NL-OMON22605

Source
Nationaal Trial Register

Health condition

drug interaction, ambulatory cancer patients, OTC drugs.

Sponsors and support

Primary sponsor: VU university medical center, Zaans Medical Center
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The aim of the present study is to gain more insight into the prevalence of interactions and duplicate prescriptions among cancer patients being treated in the outpatient day care departments for oncology and hemato-oncology. This will be the first study into the prevalence of drug interactions with OTC-drugs in cancer patients.

Secondary outcome

Possible risk factors for the occurrence of these drug-related problems will also be studied.

Study description

Background summary

The pharmacotherapeutic treatment of patients with cancer is generally associated with multiple side-effects. Drug interactions and duplicate prescriptions between anti-cancer drugs or interactions with medication to treat comorbidity can reinforce or intensify side-effects. The aim of the present study is to gain more insight into the prevalence of drug interactions and duplicate prescriptions among patients being treated in the outpatient day care departments for oncology and hematological illnesses. This will be the first study into the prevalence of drug interactions with OTC-drugs in cancer patients.

Study objective

The pharmacotherapeutic treatment of patients with cancer is generally associated with multiple side-effects. The cause of the side-effects is usually due to the toxicity of the drugs themselves. In addition, drug interactions can intensify side-effects. In general, interactions are the cause of approximately 20-30% of all drug side-effects, of which 70% needs clinical attention and 1-2% is even life-threatening [1]. Cancer patients are particularly susceptible to drug interactions [2]. In addition to chemotherapy, cancer patients often use co-medication to treat cancer related pain and venous thrombosis or to reduce the side-effects of the anti-cancer drugs. Interactions with drugs used to treat comorbidities can also occur.

Study design

Before or during administration of cytotoxic drugs.

Intervention

The patients are asked to complete a short questionnaire followed by an interview. The questionnaire contains questions about the demographic characteristics (available online as appendix). A list of the medication used to treat comorbidities for a period of six months prior to the study is requested from the patients' community pharmacy and this is discussed in the interview with the patient. During this interview the patient is also asked about the comorbidity and the use of OTC drugs. Data about the use of anti-cancer drugs, diagnose, aim of treatment (palliative/adjuvant), treatment start date and cancer-related co-medication is gathered by medical chart review and, if necessary, in an interview with the prescribing doctor. The most recent renal function (creatinine) value and liver function parameters (ASAT, ALAT and ã-GT) is obtained from the laboratory database of the hospital.

Contacts

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Eligibility criteria

Inclusion criteria

All patients with solid and hematologic malignancy currently using systemic anti-cancer drugs are asked to participate in the study.

Exclusion criteria

1. Unable to fill out questionnaires;

2. The use of trial medication;

3. A lack of command of the Dutch language;

4. Younger than 18 years old.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2009
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-03-2010
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	NL2121
NTR-old	NTR2238
Other	METC VUmc : 2009/137
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A