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Potential drug interactions among cancer patients using oral cytostatic drugs: a prevalence study

Submission date
13/12/2011

Recruitment status
No longer recruiting

Registration date
20/02/2012

Overall study status
Completed

Last Edited
29/10/2015

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A drug-drug interaction (DDI) is when a drug affects the activity of another drug when both are given together. Although some DDIs can be beneficial, most DDIs cause adverse reactions. Patients with cancer are particularly at risk for DDIs because they receive a large number of different drugs. Most cancer patients are also aged over 65 and so are likely to have other illnesses for which they also receive drug treatment. Over the past years there has been an increase in the number of oral anticancer drugs. The greater convenience and flexibility of oral treatment offers cancer patients a better quality of life, but patients on oral anticancer drugs are at considerable risk for DDIs. The aim of this study is to investigate the prevalence of DDIs among cancer patients on oral anticancer treatment.

Who can participate?
Patients aged over 18 who are receiving oral anticancer treatment.

What does the study involve?
We search the medication prescription system of the outpatients hospital pharmacy for the use of oral anticancer drugs within the previous 12 months. We obtain data on the type of oral anticancer drugs, supportive care and other drugs prescribed over the past 12 months, and collect information concerning the type of cancer, any other illnesses, and kidney and liver test results.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Maastricht University Medical Centre (Maastricht), Radboud University Medical Centre (Nijmegen) and Deventer Hospital (Deventer).

When is the study starting and how long is it expected to run for?
January to June 2012.

Who is funding the study?
Maastricht University Medical Centre (Netherlands).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Potential drug interactions among cancer patients using oral cytostatic drugs: a multicenter cross-sectional study

Study objectives
The aim of this study is to investigate the prevalence of DDIs (Drug-Drug Interactions) among ambulatory cancer patients on oral anticancer treatment. The secondary objective is to gain more insight into possible determinants for the occurrence of these DDIs.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics board of Isala Clinics, 24/03/2011, ref: 11.0334N

Study design
Multicenter cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer

Interventions
To identify the patients a search is conducted in the computer based medication prescription system of the outpatients hospital pharmacy for delivery of oral anticancer drugs in the previous 12 months. Anticancer drugs are defined as oncolytic drugs, immunomodulators and antihormonal agents. To obtain data on type of oral anticancer drugs, supportive care and comedication an overview of drugs prescribed over the past 12 months is obtained from the outpatient hospital pharmacy.

Drugs used on a continuous base and incidental use (e.g. dexamethasone during chemotherapy) are included in this study. Information concerning type of cancer and comorbidities are collected by medical chart review. Renal function [creatinine] and liver function tests [aspartate aminotransferase (AST), alanine aminotransferase (ALT) and ×-glutamyltransferase (×-GT)] are extracted from the laboratory database of the hospital.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To investigate the prevalence of DDIs among ambulatory cancer patients on oral anticancer treatment

Secondary outcome measures
To gain more insight into possible determinants for the occurrence of these DDIs

Overall study start date
01/01/2012

Completion date
01/06/2012

Eligibility

Key inclusion criteria
All ambulatory patients with the diagnosis solid tumour or a malignant haematological disease who are receiving oral anticancer therapy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. The use of experimental trial agents
2. Age <18 years
3. The use of oral anticancer drugs for non-oncological diseases

Date of first enrolment
01/01/2012

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Maastricht University Medical Centre
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Sponsor information

Organisation
Maastricht University Medical Centre (Netherlands)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maastricht University Medical Centre (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration