

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

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| Submission date 13/12/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 20/02/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 29/10/2015 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
Dr Roelof van Leeuwen
r.w.f.vanleeuwen@erasmusmc.nl

Contact information

Type(s)
Scientific

Contact name
Dr Roelof van Leeuwen

Contact details
Prof. Debyelaan 25
Dept. of Clinical Pharmacy and Toxicology
Maastricht
Netherlands
6229HX
+31 (0)43 387 1881
r.w.f.vanleeuwen@erasmusmc.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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 α -glutamyltransferase (α -GT)] are extracted from the laboratory database of the hospital.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Maastricht

Netherlands

6229HX

Sponsor information**Organisation**

Maastricht University Medical Centre (Netherlands)

ROR

<https://ror.org/02d9ce178>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Maastricht University Medical Centre (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration