The incidence of, and risk factors for liver disorders related to drugs

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To answer 3 questions: What is the incidence of drug induced liver disorders in a population during ordinarily circumstances?Which drugs are associated with an increased risk of liver disorders?Are there genetic mutations which could explain (...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON33992

Source
ToetsingOnline

Brief title
Hepatotoxicity

Condition

- Hepatic and hepatobiliary disorders

Synonym
Drug Induced Liver Injury; Hepatotoxicity

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Europese Unie (Eudragene)

Intervention

Keyword: DILI, Hepatotoxicity, IPCI, Liver toxicity

Outcome measures

Primary outcome

Incidence of drug induced liver disorders in an unselected population in

general circumstances.

Relative risk of certain liver disorders when using certain medications.

Genetic role in hepatotoxicity.

Secondary outcome

Risk profile of different medications

Study description

Background summary

There is little information on the incidence of liver disorders in the general (unselected) population. Liver disorders caused by drugs are one of the most dreaded side effects. In the last years the most frequent cause of drug withdrawal or suspension in the European Union were liver disorders.

Study objective

To answer 3 questions:
What is the incidence of drug induced liver disorders in a population during ordinarily circumstances?
Which drugs are associated with an increased risk of liver disorders?
Are there genetic mutations which could explain (partially) this hepatotoxicity?

Study design

We want to perform a retrospective cohort study using the Integrated Primary Care Information (IPCI) database. This longitudinal observational database is a general practitioner (GP) research database, containing over 800.000 computer-based patient records, obtained from a group of more than 150 GP*s

throughout the Netherlands. This database was established in 1992 by the Department of Medical Informatics of the Erasmus University Medical Centre Rotterdam in the Netherlands, with the specific purpose to conduct epidemiological and pharmaco-economic studies and post-marketing surveillance.

Study burden and risks

Filling out a questionnaire and taking of 3x10cc bloedsamples .

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who present themselves to the GP with clinical symptoms and complaints which

could be related to liver damage, and who have at least òr an ALAT value of >2 times the normal value, òr who have a combination of a raised ASAT, alkalic phosfatase, and bilirubin, where at least one of these 3 had to be >2 times the normal value

Exclusion criteria

cancer/carcinoma, liver injury or another form of hepatitis, cholelithiasis, cholecystitis, acute or chronic pancreatitis, heart failure, alcohol abusus, HIV infection, medical history< 1 yr in IPCI database

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	26-10-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL26253.078.09