CHARACTERISATION OF PROTEOMIC PROFILES PREDICTIVE OF HEPATOTOXICITY ASSOCIATED WITH ANTI-TUBERCULOSIS DRUGS: A PILOT STUDY

First published: 29/10/2010

Last updated: 03/09/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1662

EU PAS number

EUPAS1661

Study ID

1662

DARWIN EU® study

No

Study countries

Spain

Study description

Tuberculosis represents nowadays one of the main problems in public health both in non-developed as in developed countries. The increase of the incidence of tuberculosis during the last years has been related to an increase in complications derived from its treatment, based on the use of isoniazid, rifampicin and pyrazinamide, as well as to the appearance of resistance, therapeutic failure or hepatotoxicity. In particular, hepatotoxicity due to anti-tuberculous drugs is a relevant problem for the scientific community as it results in the modification of the treatment and in liver transplantation or death in the most extreme situations.We propose the study of a cohort of patients who initiate treatment or profilaxis with antituberculous drugs, with the aim of identifying those presenting a high risk of developing hepatotoxicity. Therefore, we propose the analysis of the serum proteomic profiles of these patients. The main goal is the identification and characterisation of biological markers which would be predictive of hepatotoxicity associated with anti-tuberculous drugs.

Study status

Ongoing

Research institution and networks

Institutions

Fundació Institut Català de Farmacologia (FICF)

Spain

First published: 29/03/2010

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Clinical Pharmacology Department, Area del Medicament, Hospital Clínic de Barcelona

Spain

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Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Parc de Salut Mar Barcelona (PSMAR)

Spain

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Institution | Hospital/Clinic/Other health care facility

Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau – IIB Sant Pau

First published: 01/02/2024

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Institution

Hospital de Sant Pau Barcelona, Hospital del Mar Barcelona, Unidad de Prevención y Control de la Tuberculosis (CAP Drassanes) Barcelona

Networks

Hepatox-TBCGroup

Contact details

Study institution contact

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Primary lead investigator

Luisa Ibáñez

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 16/12/2008

Study start date
Planned: 01/04/2009

Actual: 01/09/2009

Date of final study report
Planned: 31/12/2012

Sources of funding

- Other

More details on funding

ICS and FIS

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Other

If ‘other’, further details on the scope of the study

Characterisation of proteomic profiles

Main study objective:

Characterisation of proteomic profiles

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Hepatotoxicity

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

500

Study design details

Outcomes

The main goal is the identification and characterisation of biological markers which would be predictive of hepatotoxicity associated with anti-tuberculous drugs. To determine plasma protein levels before the treatment, at 21 days after initiation the treatment and at the end of the treatment.

Data analysis plan

Data analysis plan- Cox regression model for Hazard rate estimation.- Close monitoring of included and excluded patients in each participating centre.- Use of structured questionnaire for retrieval of drug use.- Use of Cox regression model for risk and confounding factors.- Inclusion of centers with the highest follow-up rate of tuberculosis in Barcelona area.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No