Identification of drug-induced liver injury (DILI) cases in Spain, a national DILI registry (Spanish DILI Registry)

First published: 09/11/2012

Last updated: 25/08/2022

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48726

EU PAS number

EUPAS3145

Study ID

48726

DARWIN EU® study

No

Study countries

☐ Spain

Study description

This is a national study that aims to identify drug-induced liver injury (DILI) cases in Hepatology and Clinical Pharmacology units in Spain. This study contains more than 50 clinical units that has sent potential hepatotoxicity cases to the coordinating center in Malaga (using a structured protocol), where the cases are diagnosed as being or not being drug-induced liver injury cases based on the corresponding clinical data acquired by the physician in charge at the collaborating unit. Clinical and demographical data are entered in to a common data base to be used for epidemiological and causality assessment studies. With the patients consent biological samples are also collected, stored in a biobank and used in biomarker identification studies

Study status

Ongoing

Research institutions and networks

Institutions

Spanish DILI Registry

Spain

First published: 13/12/2010

Last updated: 28/08/2023

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

Networks

Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas (CIBERehd)

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Network

Contact details

Study institution contact

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Primary lead investigator

M Isabel Lucena

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/06/1999

Study start date

Actual: 03/01/1994

Data analysis start date
Actual: 01/06/2001

Date of final study report
Planned: 30/06/2025

Sources of funding

- EU institutional research programme
- Other

More details on funding

Agencia Española del Medicamentos y Productos Sanitarios, FISS, MINIM, SAFE-T

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:

Not applicable

Scope of the study:

Disease epidemiology

Main study objective:

Define the main characteristics of patients, type of liver injury, outcome and culprit drugs involved in drug-induced liver injury (DILI), which will serve to guide epidemiologic and genetic studies in order to improve DILI causality assessment and diagnosis

Study drug and medical condition

Medical condition to be studied

Drug-induced liver injury

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

1500

Study design details

Outcomes

Enhance the knowledge of DILI using collected data for epidemiology and underlying mechanism studies. Generate/amplify signals of risk with the use of new and old drugs that can lead to adoption of regulatory measures ranging from changes in product labeling information to drug withdrawal.

Data analysis plan

All data will be analysed in a descriptive manner, no formal hypotheses will be tested. DILI frequencies and incidence rates will be summarized and reported to the Spanish Medicines Agency (Agencia Española del Medicamentos y Productos Santiarios). Clinical characteristics will be analyzed by frequency and percentages for categorical variables and by mean with standard deviation for continuous variables. Risk estimations will be calculated in the form of Odds Ratio. Multiple regression logistic models will be used for identification of independent variables associated with risk.

Documents

Study publications

Medina-Caliz I, Garcia-Cortes M, Gonzalez-Jimenez A, Cabello MR, Robles-Diaz M,...

Andrade RJ, Lucena MI, Fernández MC, Pelaez G, Pachkoria K, García-Ruiz E, et a...

Medina-Cáliz I, Robles-Díaz M, García-Muñoz B, Stephens C, Ortega-Alonso A, Gar...

Stephens C, Robles-Diaz M, Medina-Caliz I, Garcia-Cortes M, Ortega-Alonso A, Sa...

Robles-Díaz M, Lucena MI, Kaplowitz N, Stephens C, Medina-Cáliz I, González-Jim...

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