ACUTE AND CHRONIC ACETAMINOPHEN OVERDOSE IN PEDIATRIC POPULATION: PROSPECTIVE STUDY OF COHORT TO EVALUATE CLINIC FACTORS AND BIOMARKERS TO PREDICT DEVELOPMENT OF HEPATOTOXICITY/SOBREDOSIS AGUDA Y CRÓNICA DE PARACETAMOL EN POBLACIÓN PEDIÁTRICA: ESTUDIO PROSPECTIVO DE COHORTES PARA EVALUAR LOS FACTORES CLINICOS Y BIOMARCADORES PREDICTORES DE HEPATOTOXICIDAD (GEIPA-2012-01)

First published: 09/01/2013

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Study Planned

Administrative details

EU PAS number

EUPAS3276

Study ID

49518

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Acetaminophen is the main drug causing acute liver failure in some countries like the United States, UK and other European countries. Acetaminophen hepatotoxicity generally does not appear until several hours and even days after intake, which makes the detection of liver damage often delayed. One reason is that there is not available a biomarker of liver damage efficient to detect liver damage in early stages. The development of acetaminophen toxicity biomarkers could have important clinical implications for groups of patients who can not apply the Rumack-Matthew nomogram, e.g. arrive to the hospital at a late stage (> 24 hours after ingestion), chronic ingestion of acetaminophen, acute ingestion in alcoholic patients, concomitant intake of other drugs which could change the kinetics of acetaminophen and intake of sustained release of acetaminophen. The identification of new biomarkers that are specific to acetaminophen intoxication could be useful in the evaluation of children with acute liver failure of unknown etiology, in addition to predict the occurrence of liver damage in its early stage. Objectives of this study are 1.-To determine the clinical factors and biomarkers (pharmacokinetic, genetic and metabonomics) that predict the development of hepatotoxicity in paediatric population following acute and chronic intake of acetaminophen and 2.-Develop a predictive model to assess the risk of hepatotoxicity in acute and chronic intoxication by acetaminophen suited to paediatric patients for use in

clinical practice.

Study status

Planned

Research institutions and networks

Institutions

Hospital La Paz

First published: 01/02/2024

Last updated: 01/02/2024

Institution

School of Medicine

Hospital Universitario 12 de Octubre

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Hospital Universitario "La Paz" Madrid, Spain, Hospital Universitario "Gregorio Marañón" Madrid, Spain, Hospital Universitario "Niño Jesús" Madrid, Spain, Hospital Universitario "12 de Octubre" Madrid, Spain

Contact details

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Study contact

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Primary lead investigator

Elena Ramírez García

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/01/2013

Study start date

Planned: 30/01/2013

Data analysis start date
Planned: 01/06/2018

Date of final study report
Planned: 30/09/2022

Sources of funding

- Other

More details on funding

Clinical Pharmacology Department, HULP, UAM

Study protocol

Protocolo[GEIPA-2012-01]Venmienda.pdf (207.75 KB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Other

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

Biomarkers detection, pharmacokinetics

Main study objective:

1. To determine the clinical factors and biomarkers (pharmacokinetic, genetic and metabonomics) that predict the development of hepatotoxicity in paediatric population following acute and chronic intake of acetaminophen.2. Develop a predictive model to assess the risk of hepatotoxicity in acute and chronic intoxication by acetaminophen suited to paediatric patients for use in clinical practice

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Pharmacokinetic study, Pharmacogenetics, metabonomics

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02BE01) paracetamol

paracetamol

Medical condition to be studied

Hepatotoxicity

Population studied

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

180

Study design details

Data analysis plan

To estimate differences between variables are used chi-square or T student if parametric. And if it does not follow a normal distribution, nonparametric tests will be used. To determine the factors associated with liver damage will design a multivariate logistic regression where the dependent variable is the presence of hepatotoxicity and a multivariate linear regression to determine the relationship between transaminase values and factors (demographic, clinical, kinetic, analytical, genetic and metabonómics).

Documents

Study publications

Tong HY, Medrano N, Borobia AM, Ruiz JA, Martínez AM, Martín J, Quintana M, Gar…

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

2013-0014_DoI signed-SDPP-3276.pdf (175.26 KB)

Composition of steering group and observers

EUPAS3276-3327.pdf (23.73 KB)

Signed code of conduct

2013-0014_Declaration of compliance with ENCePP CoC-SDPP-3276.pdf (34.01 KB)

Signed code of conduct checklist

2013-0014_Checklist of CoC for studies-SDPP-3276.pdf (476.4 KB)

Signed checklist for study protocols

2013-0014_Checklist for Study Protocol-SDPP-3276.pdf (164.92 KB)

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