HLA alleles as genetic risk factors for elevation of aminotransferase levels in patients treated with agomelatine

First published: 24/06/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS10039

Study ID

28494

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

To assess and investigate some susceptibility factors (allelic variants of HLA system) for agomelatine’s effect on serum aminotransferase levels

Study status

Finalised

Research institutions and networks

Institutions

DALY

Contact details

Study institution contact

Christèle PERCHERON christele.percheron@servier.com

Study contact

christele.percheron@servier.com

Primary lead investigator

Ann K. DALY

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/05/2014

Study start date
Actual: 20/04/2009

Date of final study report
Planned: 30/09/2016

Actual: 26/09/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Les Laboratoires Servier

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

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

Pharmacogenomy

Data collection methods:

Secondary use of data

Main study objective:

To assess and investigate the relevance of certain genetic susceptibility factors (HLA allelic variants) to the increased serum transaminases (>3ULN) seen in some patients treated with agomelatine.

Study Design

Non-interventional study design

Case-control

Other

Non-interventional study design, other

Pharmacogenomics

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06AX22) agomelatine

agomelatine

Medical condition to be studied

Major depression

Generalised anxiety disorder

Population studied

Short description of the study population

Patients treated with agomelatine.

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

84

Study design details

Outcomes

Genotype for selected HLA genes (HLA class I : A, B and C genes and HLA class II : DRB1, DQA1, DQB1, and DPB1genes)

Data analysis plan

For each HLA gene, the association between genotype and case / control status will be evaluated with a logistic regression model. Based on this method an Odds-Ratio with its 95% CI and a p-value will be provided.

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.

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective study : Samples were obtained from different previous clinical trials with agomelatine

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

Unknown