Agomelatine Drug Utilisation Study in Selected European Countries: A Multinational, Observational Study to Assess Effectiveness of Risk-Minimisation Measures

First published: 03/02/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17678

Study ID

30635

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France

☐ Germany

☐ Spain

Study description

Non-interventional, multinational Post-Autorisation Safety Study in patients initiating agomelatine treatment in routine clinical practice in Denmark, France, Germany, and Spain. The study includes a retrospective medical data abstraction to collect patient data before and after the last minimization measures in order to evaluate adherence to the liver test monitoring regimen and compliance with relevant contraindications and a cross-sectional patient survey to assess patients' reasons for non-compliance with the liver test monitoring regimen. Medical data abstraction will collect characteristics of agomelatine users including relevant comorbidities, date, dose, and duration of agomelatine prescriptions and of fluvoxamine and/or ciprofloxacin, date of liver function tests (ALT and AST) and results. The patient survey will collect patients' characteristics, knowledge of the key liver safety information, and reasons for non-compliance with liver test monitoring when applicable.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

☐ France

☐ Spain

☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution **Not-for-profit** **ENCePP partner**

Multiple centres: 51 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lynne Hamm

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 02/05/2016

Study start date
Planned: 31/01/2017

Actual: 14/05/2017

Date of interim report, if expected
Planned: 31/07/2017

Date of final study report
Planned: 31/03/2018

Actual: 23/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Institut de Recherches Internationales Servier

Study protocol

Protocole -11.2016.pdf(912.88 KB)

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:

Drug utilisation

Other

Safety study (incl. comparative)

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

Patient survey

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To evaluate the effectiveness of additional risk minimisation measures for agomelatine before and after implementation of these measures. For the medical record abstraction: to evaluate the adherence to the liver test monitoring regimen and the compliance with relevant contraindications. For the patient survey: to evaluate patients’ reasons for non-compliance with the liver test monitoring regimen

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Post-authorization safety study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06AX22) agomelatine

agomelatine

Medical condition to be studied

Major depression

Population studied

Short description of the study population

Physician prescribers (i.e., psychiatrists and general practitioners [GPs]) practising in outpatient settings (hospital outpatient clinics, other outpatient clinics, or private practices) where outpatients treated with agomelatine are managed in Denmark, France, Germany, and Spain.

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

1600

Study design details

Outcomes

For the medical record abstraction: proportion of patients with a liver test performed before treatment or at initiation and at least one test performed during treatmentFor the survey: Proportion of patients acknowledging receipt of the patient booklet and reason for non-compliance to the liver test monitoring regimen, For the medical record abstraction : proportion of patients with a liver test performed before treatment or at initiation and a test performed at 3, 6, 12, and 24 weeks after treatment initiation—accounting for “duration of treatment” and dose escalation

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Data analysis plan

Descriptive analyses overall and by country, and, if numbers allow, by specialty. Medical record abstraction: A single estimate of the prevalence of adherence to liver test will be provided separately for each study period with 95% CIs around the point estimate. The difference between the prevalence of adherence before and after RMMs will be calculated as an estimate of the change with the 95% CI. A chi-square test or a t-test will be used to test the differences between the two study periods (before and after RMM).Patient survey: The proportion of patients acknowledging receipt of the patient booklet and the reasons for non-compliance to the liver test monitoring will be providedThe number of subjects with missing data will be reported for each variable. Descriptive analysis comparing patients with and without missing data will be conducted. To assess the potential impact of a non-random missing data pattern for adherence/compliance, a sensitivity analysis will be conducted.

Documents

Study publications

E. Jacquot, E. Collin, A. Ladner, A. Tormos, L. Hamm, S. Perez-Gutthann, L. Gut...

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective data collection in medical charts

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