Dabigatran study in the early phase of stroke. New neuroimaging markers and biomarkers study (SEDMAN STUDY)

First published: 18/03/2016

Last updated: 15/10/2018

Study Ongoing

Administrative details

EU PAS number

EUPAS12878

Study ID

26079

DARWIN EU® study

No

Study countries

Spain

Study description

SEDMAN study is a prospective multicenter study. The main idea is to look for the first time by Genome Wide Association (arrays that determine more than 1 million polymorphisms) genetic risk factors associated with response to dabigatran. To conduct the study, the goal is to recruit 300 patients with ischemic stroke with cardioembolic etiology treated with dabigatran and 200 treated with Acenocumarol to determine if genetic risk factors are associated with the occurrence of any bleeding or vascular event in a year follow-up.

Study status

Ongoing

Research institutions and networks

Institutions

Hospital Universitari Mútua Terrassa

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jerzy Krupinski

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/05/2015

Actual: 15/05/2018

Study start date

Planned: 24/03/2016

Actual: 28/06/2016

Data analysis start date

Planned: 21/03/2018

Actual: 23/04/2018

Date of final study report

Planned: 01/08/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

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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:

Other

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

Pharmacogenomics

Main study objective:

The main objective is found genetic risk factors associated with the occurrence of any bleeding or vascular event in a year follow-up in patients treated with dabigatran or acenocoumarol.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AA07) acenocoumarol

acenocoumarol

Medical condition to be studied

Embolic stroke

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

Recurrence of vascular events and any bleeding

Data analysis plan

Data will be analyzed through GWAS analysis. The results will be analyzed by experienced genotypic bioinformatics: Plink, Haploview, STATA, IMPUTE2, SNPtest, GTOOL, Galaxy managment. In addition, we have support of Spanish Consortium for Genetics of Stroke (Genestroke). The PLINK software is the main program for the analysis of GWAS. Using this software we can clean the raw results of genotyping platforms and determine the presence of risk alleles associated with resistance to the study drugs. Haploview software will be used for data management and graphics for significance analysis. STATA statistical software is a data management and very useful for the creation of Q_Q plots graphs that assist in the interpretation of genotypic results. GTOOL, SNPtest and IMPUTE2 are software for data imputation and analysis of imputed data through the information available in the 1000 Genomes Project.

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)

Electronic healthcare records (EHR)

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