Burden of AV GRAft and Fistula Complications in chronic kidney disease patients (GRAFIC)

First published: 23/09/2011

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Study Ongoing

Administrative details

EU PAS number

EUPAS2192

Study ID

2193

DARWIN EU® study

No

Study countries

Germany

Spain

United Kingdom

United States

Study description

The purpose of the study is to assess the healthcare use and treatment costs associated with complications that might arise from different types of vascular access (e.g., a graft or fistula, also known as a dialysis shunt), which are used for haemodialysis

Study status

Ongoing

Research institutions and networks

Institutions

Zentrum für Nieren- und Hochdruckkrankheiten

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Institution | Educational Institution

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Primary lead investigator

Bernd Krumme

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/12/2010

Study start date

Planned: 15/09/2011

Actual: 19/09/2011

Data analysis start date

Planned: 06/11/2012

Date of final study report

Planned: 28/12/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shire Pharmaceuticals

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

The overall objective of the study is to longitudinally evaluate current standard of care and health care utilization, treatment patterns and related costs associated with VA complications in patients with chronic kidney disease Stage 4 or higher requiring an AV graft or fistula for haemodialysis

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, prospective, international, multicenter longitudinal, comparative cohort study

Study drug and medical condition

Medical condition to be studied

Chronic kidney disease

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)

Special population of interest

Renal impaired

Estimated number of subjects

1.183

Study design details

Outcomes

Evaluation of current standard of care and health care utilization, treatment patterns and related costs associated to VA complications, Baseline sociodemographic and clinical characteristics of patients will be compared according to the presence of any VA complications during the study follow-up period

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Data analysis plan

The analyzed population will include all patients recruited to the study who meet all inclusion and no exclusion criteria. A description of the study patients' sociodemographic and clinical characteristics will be reported according to the study cohorts.The rate of complications for each study group in USA and EU patients will be calculated using a CI of 95%. Types of VA complications will be also reported by study cohorts in USA and EU patients.In the cohort of patients with a maturing fistula, the percentage of fistulae reaching maturation, the failure rate during maturation period, reasons and timing for failure or complications, and the time elapsed between access creation and the initiation of the dialysis will be described.

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

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