

# 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

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### Study ID

2193

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### DARWIN EU® study

No

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### Study countries

 Germany

 Spain

 United Kingdom

 United States

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## 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

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## Study status

Ongoing

## Research institutions and networks

### Institutions

Zentrum für Nieren- und Hochdruckkrankheiten

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Institution

Educational Institution

Prof. Bernd Krumme

Dr. Castelao Barcelona, Spain, Dr. Fluck Derby, UK, Dr. Besarab Detroit, MI, USA

## Contact details

### **Study institution contact**

Bernd Krumme [krumme@nephrologie-wiesbaden.de](mailto:krumme@nephrologie-wiesbaden.de)

Study contact

[krumme@nephrologie-wiesbaden.de](mailto:krumme@nephrologie-wiesbaden.de)

### **Primary lead investigator**

Bernd Krumme

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 20/12/2010

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### **Study start date**

Planned: 15/09/2011

Actual: 19/09/2011

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### **Data analysis start date**

Planned: 06/11/2012

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### **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

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#### **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

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## **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)
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## **Special population of interest**

Renal impaired

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## **Estimated number of subjects**

1183

# 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

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No