Long-term outcomes in patients treated with ADVAGRAF following standard criteria donor or expanded criteria donor kidney transplant in routine clinical practice in Europe: a multicenter secondary data (chart review) cohort study

First published: 12/06/2025

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000589

Study ID

1000000589

DARWIN EU® study

No

Study countries

France

Germany

Spain

Study description

ADVAGRAF is a medicine used after kidney transplants to stop the immune system from rejecting the new kidney. This study will use information from clinics in Europe to learn more about the outcomes of kidney transplants treated with ADVAGRAF. This type of study is called a real-world study.

Study status

Finalised

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Alexander Harkavyi

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 03/07/2024

Study start date
Actual: 29/07/2025

Data analysis start date
Planned: 31/03/2026

Actual: 10/04/2026

Date of final study report
Planned: 31/10/2026

Actual: 20/10/2026

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

506-MA-3552

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This study is a secondary data project designed as a retrospective, non-interventional, observational, multi-center chart review conducted in adult patients, who underwent standard criteria donor or expanded criteria donor kidney transplant and received ADVAGRAF-based therapy.

Main study objective:
The main aim of this study is to collect information about the long-term outcomes of kidney transplants treated with ADVAGRAF in Europe. Researchers will also learn how factors like sex, age, bodyweight, and other treatments might affect transplant outcomes.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medicinal product name
ADVAGRAF

Study drug International non-proprietary name (INN) or common name
TACROLIMUS

Anatomical Therapeutic Chemical (ATC) code
(L04AD02) tacrolimus
tacrolimus

Population studied

Short description of the study population

The people in this study will have had a kidney transplant from a donor under 50 years of age (standard criteria donor), or over 50 years of age (expanded criteria donor). They had their kidney transplants between 2008 and 2014 and were treated with ADVAGRAF.

Age groups

- **Adult and elderly population (≥18 years)**

Estimated number of subjects

180

Study design details

Outcomes

1. Patient survival: Time to death, Cumulative mortality at the end of follow-up.
2. Graft survival: Time to graft failure, Cumulative incidence of overall graft failure at the end of follow-up, Time to death-censored graft survival, Cumulative incidence of death-censored graft failure at the end of follow-up.

Data management

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