Long-term outcomes in patients continuously treated with ADVAGRAF following a liver transplant in routine clinical practice in Spain: a multicenter secondary data (chart review) cohort study

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000603

Study ID

1000000603

DARWIN EU® study

No

Study countries

☐ Spain

Study description

ADVAGRAF is a medicine given to people just after they receive a liver transplant to stop the immune system from rejecting the new liver.
This study will use information from clinics in Spain to learn more about the outcomes of people treated with ADVAGRAF after their liver transplant in Spain. This type of study is called a real-world study.
Information will be collected from medical records from the start of ADVAGRAF treatment until the transplant failed, treatment stopped, or until 31 December 2024.

Study status

Ongoing

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

Networks

N/A

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

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Primary lead investigator
Alexander Harkavyi

Primary lead investigator

Study timelines

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

Study start date
Actual: 21/11/2024

Data analysis start date
Planned: 30/01/2026

Date of final study report
Planned: 30/11/2026

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-3551

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Healthcare resource utilisation

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 18 years old and over, who underwent whole liver transplantation and received ADVAGRAF therapy.

Main study objective:

The main aim of this study is to collect information about the long-term outcomes of people treated with ADVAGRAF in Spain.
Researchers will learn about the health of people treated with ADVAGRAF. They will also learn how other factors affect long-term outcomes.
This includes their age, sex, kidney health, and how severe their liver disease was before the transplant. This will be for people treated with ADVAGRAF after their liver transplant.

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 study will include people who had a liver transplant between 2008 and 2014 and were treated with ADVAGRAF.

Age groups

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

Estimated number of subjects

150

Study design details

Comparators

N/A

Outcomes

1. Patient survival: Time to death; Cumulative mortality at the end of follow-up

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

Data management

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.

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