Evaluation of the effectiveness of the belatacept (Nulojix®) Patient Alert Card in patients following renal transplantation in European Economic Area countries.

First published: 24/06/2015

Last updated: 03/06/2026

Study | Finalised

Administrative details

EU PAS number

EUPAS10046

Study ID

22739

DARWIN EU® study

No

Study countries

Austria

France

Germany

Sweden

Study description

This was a non-interventional observational study designed to evaluate the effectiveness of the belatacept (Nulojix®) Patient Alert Card (PAC) as an additional risk minimization measure in renal transplant patients. The study consisted of three epidemiological sub-studies: (1) a patient survey assessing awareness, distribution, utilization, utility, knowledge, comprehension, and implementation of key safety messages contained in the PAC; (2) a healthcare professional (HCP) survey assessing the same outcomes among nephrologists and nurses; and (3) a Clinical Outcomes Study using retrospective chart review to evaluate whether patients' understanding and implementation of key safety messages were associated with clinical and safety outcomes, particularly serious infections.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

Last updated: 03/06/2026

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 05/08/2014

Actual: 05/08/2014

Study start date

Planned: 01/10/2016

Actual: 01/10/2016

Date of final study report

Planned: 15/01/2018

Actual: 25/01/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol Myers Squibb

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Non-interventional observational study comprising a patient survey, an HCP survey and a retrospective chart review evaluating awareness, understanding and implementation of key PAC messages and their association with clinical outcomes.

Main study objective:

The main objective of the study was to evaluate the effectiveness of the belatacept (Nulojix®) Patient Alert Card by assessing distribution, awareness, utilization, utility, knowledge, comprehension and behaviour among patients and healthcare professionals, and by evaluating the association between these measures and clinical outcomes in patients

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Healthcare professional survey, patient survey, retrospective chart review study

Study drug and medical condition

Medicinal product name

NULOJIX

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

BELATACEPT

Anatomical Therapeutic Chemical (ATC) code

(L04AA28) belatacept

belatacept

Medical condition to be studied

Renal transplant

Population studied

Short description of the study population

Adult renal transplant patients treated with belatacept (Nulojix®) within the previous 3 months and healthcare professionals (nephrologists and nurses) involved in prescribing, administering or managing belatacept-treated patients within the previous 6 months.

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

Other

Special population of interest, other

Patients with renal transplantation

Estimated number of subjects

70

Study design details

Setting

The study was conducted in France, Germany, Sweden and Austria in hospital and physician renal units. Eligible patients were adult renal transplant recipients who had received belatacept within the previous 3 months. Eligible HCPs were nephrologists and nurses involved in prescribing, administering or managing belatacept-treated patients within the previous 6 months.

Outcomes

Patient survey: awareness, distribution, utilization, utility, knowledge/comprehension, behaviour and overall understanding and implementation of PAC messages.

HCP survey: awareness, distribution, utilization, utility, knowledge/comprehension, behaviour and overall understanding and

implementation of PAC messages.

Clinical outcomes study: serious infections and infections leading to hospitalization (primary outcomes); infections leading to discontinuation, time from infection symptom onset to medical attention or treatment, and time from transplantation to biopsy-confirmed graft rejection (secondary outcomes).

Data analysis plan

Descriptive analyses estimated awareness, distribution, utilization, utility, knowledge, comprehension and behaviour outcomes. Univariate and multivariable regression analyses were used to identify determinants of understanding and implementation. Associations between understanding/implementation scores and clinical outcomes were evaluated using regression methods and Kaplan–Meier analyses where appropriate.

Summary results

Among patients, 27% were aware of the PAC, 94% of those aware reported receiving it and 77% had read it. Knowledge, utility and behaviour scores were higher among patients who recalled receiving the PAC. Among HCPs, 69% were aware of the PAC and 58% had accessed it. Serious infections were more frequent among patients with lower understanding and implementation scores, although the association was not statistically significant. The PAC appeared to contribute to patient-HCP communication but was not systematically incorporated into clinical care.

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)

Other

Patient surveys

Data sources (types), other

Web-based healthcare professional survey, paper survey for patients and retrospective chart review study using an electronic case report form.

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