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: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10046

Study ID

22739

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] France
- [ ] Germany

Sweden

Study description

This is a study that evalustes the effectiveness of the belatacept patient alert card (PAC). Three epidemiological sub-studies will be conducted to make this evaluation: a patient survey of understanding and implementation of the key messages in the belatacept PAC, a health care professional (HCP) survey of understanding and implementation of the key messages in the belatacept PAC and a a Clinical Outcomes Study using retrospective chart review to correlate clinical and safety outcomes with levels of understanding and implementation of the key messages in the PAC.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution **Laboratory/Research/Testing facility** **Non-Pharmaceutical company**

ENCePP partner

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Nawab Qizilbash MBChB MRCP(UK) BSc MSc DPhil(Oxon.)
n.qizilbash@oxonepi.com

Study contact

n.qizilbash@oxonepi.com

Primary lead investigator

Nawab Qizilbash MBChB MRCP(UK) BSc MSc DPhil(Oxon.)

Primary lead investigator

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:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The main objective of the study is to evaluate the effectiveness of the belatacept patient alert card (PAC) in renal transplantation patients via three epidemiological sub-studies: a patient survey, a healthcare professional (HCP) survey and a clinical outcomes study using retrospective chart review.

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

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

BELATACEPT

Medical condition to be studied

Renal transplant

Population studied

Short description of the study population

Patients/HCPs with responses to each question that indicate effectiveness of the belatacept (Nulojix®) Patient Alert Card (PAC).

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

Outcomes

Patient survey: proportion of correct responses to individual questions about receipt, knowledge, understanding and acting on the advice contained in the belatacept PAC.HCP survey: proportion of correct responses to individual questions about understanding and implementation of key messages contained in the PAC.Clinical outcomes study: proportion of serious infections. Patient survey:determinants of patient knowledge and understanding and implementation of the key messages. HCP survey:determinants of HCP understanding and implementation of the key messages. Clinical outcomes study:proportion of infections leading to discontinuation, mean time from symptom onset of infection to receipt of medical therapy and mean time from transplantation to graft rejection.

Data analysis plan

For the patient and HCP questionnaires, the percentage of patients/HCPs with responses to each question that indicate effectiveness of the PAC will be determined: receipt, awareness, usage, knowledge and comprehension of key messages. The primary endpoints of the patient survey responses indicating understanding and implementation will be analysed by baseline patient characteristics. The primary endpoints of the HCP survey responses indicating understanding and implementation of the PAC will be analysed by baseline HCP characteristics. Correlation between patients' degree of understanding and implementation of the messages in the PAC with serious infections and other secondary endpoints will be studied through regression techniques.

Data management

Data sources

Data sources (types)

Other

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