NIS Xtra (Verträglichkeit und Wirksamkeit von Safinamid)

First published: 25/07/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS20021

Study ID

20022

DARWIN EU® study

No

Study countries

Germany

Study description

Verträglichkeit und Wirksamkeit von Safinamid (Xadago) als Zusatztherapie zu Levodopa bei Patienten mit idiopathischer Parkinson-Krankheit im mittleren bis Spätstadium - eine nicht-interventionelle Studie zur Beobachtung der

routinemäßigen Anwendung in der neurologischen Praxis in Deutschland.

Study status

Ongoing

Research institutions and networks

Institutions

Prof. Jost

Contact details

Study institution contact

Wolfgang Jost info@parkinson-klinik.de

Study contact

info@parkinson-klinik.de

Primary lead investigator

Wolfgang Jost

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/05/2015

Study start date
Actual: 03/09/2015

Data analysis start date
Actual: 12/06/2017

Date of final study report
Planned: 15/09/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zambon GmbH

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Other study registration identification numbers and links

Bfarm Number. 6640

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

Verträglichkeit und Wirksamkeit von Safinamid

Study drug and medical condition

Medicinal product name

XADAGO

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)

Estimated number of subjects

250

Study design details

Data analysis plan

Nicht-interentionelle Studie zur Beobachtung der routinemäßigen Anwendung in der neurologischen Praxis in Deutschland

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No