Actual conditions of use of OraVerse® in patients among resident dentists throughout Germany (OraDUS)

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Study Finalised

Administrative details

EU PAS number

EUPAS11650

Study ID

11651

DARWIN EU® study

No

Study countries

☐ Germany

Study description

A retrospective, observational, cross-sectional drug utilisation survey among resident dentists throughout Germany to investigate the conditions of use of OraVerse® after local anesthetic procedures in daily routine clinical practice, and to investigate the use of OraVerse® according to labelling.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

Clinical Study Unit and Winicker Norimed

Contact details

Study institution contact

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Primary lead investigator

Monika Daubländer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/04/2014

Study start date

Planned: 01/05/2014

Actual: 10/04/2014

Date of final study report

Planned: 01/01/2015

Actual: 16/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi-Aventis Deutschland GmbH

Study protocol

A-301410_ORADUS_NIS_Protocol_LR.pdf.PDF(1.5 MB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The outcomes of interest will be the conditions of use of treatment. The primary outcomes will be the incidence of patients who “comply” / “not comply” with the recommendations in the SmPC regarding the following points:• Patient age class• Body weight class• Type of dental intervention• Local anesthetic used (product and dose)• Dose of OraVerse® used

Study drug and medical condition

Name of medicine, other

OraVerse

Population studied

Short description of the study population

Patients treated with OraVerse® after local anesthetic procedure (with a local anesthetic containing a vasoconstrictor) by dentists within the last 3 months before contract signing.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

523

Study design details

Outcomes

The primary outcome was the proportion of patients that ‘comply’/’not comply’ with the conditions of use of OraVerse® according to the specifications in the Summary of Product Characteristics (SmPC). Dental interventions considered

routine interventions were specified by the Company after discussion with the clinical expert.

Data analysis plan

Data collection: Dentists reported on conditions of use of OraVerse® from individual patients on ‘per-patient’ documentation forms.Safety data collection: retrospective detection of safety signals.Data management, review, validation: data collection was completely anonymous as requested by the authorities. Therefore, no backtracking was possible and no data quality control at site level was performed.Summary of statistical methods used: Data management and statistical analysis were performed using SAS, version 9.2. All study data were analyzed in an exploratory fashion by means of descriptive statistics.Compliance analysis: For the analysis of the primary outcome, the proportions of compliance and of non-compliance with the specifications in the SmPC were calculated for all compliance variables separately.

Documents

Study results

Oradus_StudyReport_incl_Appendices_V3.3_20141216_incl approval.pdf(1.97 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Product registry, registry number : PHENLL07113

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