A non-interventional, observational study in Germany to evaluate the effectiveness of reversal of local anesthesia and occurrence of adverse events in patients treated with OraVerse® in dental office (OraNIS)

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Study | Finalised

Administrative details

EU PAS number

EUPAS11634

Study ID

11635

DARWIN EU® study

No

Study countries

Germany

Study description

OraNIS was a prospective, multicenter, open-label, non-controlled, non-interventional, observational study among practicing dentists throughoutGermany in order to document the effectiveness and safety of OraVerse® afterlocal anesthetic procedures in daily routine clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

Clinical Study Unit and Winicker Norimed

15 centers Baden-Württemberg, 53 centers Bayern, 11 centers Berlin, 3 centers Brandenburg, 1 center Bremen, 4 centers Hamburg, 20 centers Hessen, 1 center Mecklenburg-Vorpommern, 9

centers Niedersachsen, 30 centers Nordrhein-Westfalen

Contact details

Study institution contact

Frank Liebaug frankliebaug@hotmail.com

Study contact

frankliebaug@hotmail.com

Primary lead investigator

Frank Liebaug

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/10/2013

Study start date

Actual: 05/11/2013

Date of final study report

Actual: 27/08/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi-Aventis Deutschland GmbH

Study protocol

A-301179_ORA_NIS_Beobachtungsplan_LR.pdf.PDF (1.51 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:

Assessment of risk minimisation measure implementation or effectiveness
Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objectives were to investigate patients treated with OraVerse® after local anesthesia with an anesthetic containing epinephrine (adrenalin) as part of a routine dental procedure in terms of- Time to recovery of normal sensation in the lip/tongue.- Time to recovery of normal function (eating, drinking and speaking).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, multicenter, open-label, non-controlled, non-interventional, observational study

Study drug and medical condition

Medicinal product name, other

OraVerse

Population studied

Short description of the study population

Patients that were treated with OraVerse® for reversal of local soft-tissue anesthesia after routine dental treatment in dental office.

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

445

Study design details

Data analysis plan

Data collection: Dentists were to report on 3 to 4 patients treated with OraVerse® on a paper case report form (CRF).Safety data collection: AEs and serious AEs (SAEs) were collected by dentists at the follow-up interviews and recorded on (S)AE report forms.Data management, review, validation: Quality checks for source data verification were done on-site as well as by phone by the CRO. Quality control was done as described in the Data Management Plan (DMP). Data were subjected to plausibility checks and implausible data were corrected or excluded from analysis as described in the Data Validation Plan (DVP).Statistical considerations:Data management and statistical analysis were done with SAS, version 9.2.All study data were analyzed in an exploratory fashion by means of descriptivestatistics.

Documents

Study results

ORANIS-StudyReport_final_150827_Redacted_summary.pdf (1.51 MB)

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