Non-interventional post-authorization study on effectiveness of reversal of local anaesthesia and on the occurrence of local reactions and cardiovascular adverse events in patients treated with OraVerse® versus patients not treated with OraVerse® (control group) in Germany (ORAPAES)

First published: 04/06/2013

Last updated: 25/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4062

Study ID

33005

DARWIN EU® study

No

Study countries

Germany

Study description

Non-interventional post-authorization study on effectiveness of reversal of local anaesthesia and on the occurrence of local reactions and cardiovascular adverse events in patients treated with OraVerse® versus patients not treated with OraVerse® (control group) in Germany

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

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Institution

Multiple centres: 12 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/12/2012

Actual: 31/12/2012

Study start date

Planned: 15/06/2013

Actual: 15/06/2013

Data analysis start date

Planned: 15/07/2014

Actual: 05/01/2015

Date of final study report

Planned: 15/06/2015

Actual: 30/06/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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:

Primary data collection

Main study objective:

-To compare time to recovery of normal sensation in the lip/tongue among patients treated with OraVerse® and not treated with OraVerse® (control group) after local anaesthetic procedures in routine clinical practice
-To compare time to recovery of normal function (eating, drinking and speaking) among patients treated with OraVerse® and not treated with OraVerse® (control group) after local anaesthetic procedures in routine clinical practice

Study Design

Non-interventional study design

Cohort
Other

Non-interventional study design, other

Prospective, post-authorization study

Study drug and medical condition

Medicinal product name, other

OraVerse

Medical condition to be studied

Cardiovascular disorder

Population studied

Short description of the study population

Patients treated with OraVerse® and not treated with OraVerse® (control group) after local anaesthetic procedures in routine clinical practice.

Patients eligible for ORAPAES were those
1. who underwent local anesthesia by intraoral, submucosal injection of a local anesthetic containing a catecholamine vasoconstrictor, such as epinephrine (adrenaline) (dilution 1:100,000 or 1:200,000), after a routine dental procedure such as teeth cleaning, calculus removal, scaling and root planing, and restoration
preparation including crown preparation;
2. Who were at least 6 years old and weighed at least 15 kilograms (33.1 pounds);
3. For whom the dentist had made a decision to administer PM independent of the participation in the study;
4. who had signed an informed consent form

Patients eligible for ORANIS were patients
1. who received local anesthesia by intraoral submucosal injection of a local anesthetic solution containing a catecholamine vasoconstrictor, such as epinephrine
(dilution 1:100,000 or 1:200,000), after a routine dental procedure (teeth cleaning, scaling and root planing, restoration preparation, or preparation for crowns);

2. who were at least 18 years old; -those for whom the dentist had made a decision to administer PM independent of this documentation;
3. who had signed an informed consent, and were included consecutively, if eligible.

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

672

Study design details

Outcomes

•Primary outcomes: Effectiveness. The primary outcomes will be the sensory and functional assessment measured by the patient the day of OraVerse® administration and collected the day after OraVerse® administration. •the patient reported time to recovery to normal:•sensation of upper lip, lower lip and tongue•functionality (speaking, drinking, eating),
•Secondary outcomes: Safety. The secondary outcomes of the study will be the frequency of local reactions (post-procedural pain, injection site pain, injection site reaction) and cardiovascular acute events (bradycardia, tachycardia, hypertension, hypotension, cardiac arrhythmia) which will be collected by the

dentist prior to discharge and during a phone call to the patient the day following the dental procedure.

Data analysis plan

•Primary objective: estimated median and corresponding 95% confidence interval of the time to recovery of normal sensation of the lip and tongue and of the time to recovery of functionality for each group (OraVerse® and control) will be calculated using the Kaplan-Meier method. (Stratified) log-rank-tests will be used to compare the survival curves of the 2 treatment groups. A Cox model with treatment group and potential confounders will be used to estimate the hazard ratio (HR) of outcome of interest using the control group as reference.
•Secondary objective: estimated frequency and corresponding 95% confidence interval of local reactions, cardiovascular events and cardiovascular events leading to healthcare consultation will be described for each group (OraVerse® and control). Logistic regression model will be used to estimate odds ratios (OR) to compare the frequency of local reactions between treatments groups after adjustment on potential confounders.

Documents

Study results

JADA_Daublaender et al._ORAPAES_ORANIS.pdf (396.79 KB)

Study publications

Daubländer M, Liebaug F, Niedeggen G, Theobald K, Kürzinger ML. Effectiveness a...

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