A Phase 4, Multicenter, Randomized, Double-Blinded, Controlled Study of OraVerse® for Safety and Efficacy in Pediatric Dental Patients Undergoing Mandibular and Maxillary Procedures

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Study Finalised

Administrative details

EU PAS number

EUPAS11647

Study ID

11648

DARWIN EU® study

No

Study countries

☐ United States

Study description

Multicenter, randomized, double-blinded, controlled study in pediatric dental patients 2 to 5 years of age undergoing Mandibular and Maxillary Procedures, whose objective was to determine the safety and tolerability of OraVerse.

Study status

Finalised

Research institutions and networks

Institutions

Novocol Pharmaceutical of Canada

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Institution

Nationwide Children's Hospital Columbus, OH, Indiana University School of Dentistry Indianapolis, IN, University of Pennsylvania School of Dental Medicine Philadelphia, PA, University of California School of Dentistry San Francisco, CA, Jean Brown research Salt Lake City, UT, University of Pittsburgh Pittsburgh, PA

Contact details

Study institution contact

Eric Penrose epenrose@septodont.com

Study contact

epenrose@septodont.com

Primary lead investigator

Joel Berg

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/08/2011

Study start date

Actual: 14/02/2012

Date of final study report

Actual: 22/03/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novocol Pharmaceutical of Canada, Inc.

Study protocol

110902_FINAL Protocol Phase 4 OraVerse PHE-11-001 V4.0.PDF(1.37 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Clinical trial

Main study objective:

The primary objective was to determine the safety and tolerability of OraVerse in subjects 2-5 years of age as measured by the incidence and severity of adverse events, clinically significant changes in vital signs and oral cavity assessments, nerve injury, and analgesics required for intraoral pain.

Study Design

Clinical trial regulatory scope

Post-authorisation interventional clinical trial

Clinical trial phase

Therapeutic use (Phase IV)

Clinical trial randomisation

Randomised clinical trial

Clinical trial types

Low-intervention clinical trial

Study drug and medical condition

Name of medicine, other

OraVerse

Population studied

Short description of the study population

Pediatric patients treated with OraVerse® for reversal of local soft-tissue anesthesia after routine dental treatment.

Age groups

Children (2 to < 12 years)

Estimated number of subjects

150

Study design details

Outcomes

Safety: The safety and tolerability of OraVerse was measured by the incidence and severity of adverse events, clinically significant changes in vital signs and oral cavity assessments, nerve injury, and analgesics required for intraoral pain. Safety: the safety and tolerability of OraVerse as measured by the incidence, severity and duration of intraoral pain and assessed by the Wong-Baker Pain Rating ScaleEfficacy: For subjects 4 and 5 years of age trainable in the pFAB and sensation procedures, the study determined if OraVerse accelerates the time to normal function and sensation of the lip and tongue as measured by the pFAB.

Data analysis plan

Eligible subjects were randomized to OraVerse or sham injection. There were 6 periods in the study: 1) screening, 2)anesthetic administration and dental procedure, 3) study drug administration, 4) observation period, 5) telephone follow-up, and 6) in-clinic safety follow-up. All subjects 2-5 years of age were assessed for safety. Subjects 4 and 5 years of age who were trainable in Wong-Baker FACES Pain Rating Scale (W-B PRS) were assessed for pain.Subjects 4 and 5 years of age who were trainable in the pediatric Functional Assessment Battery (pFAB) and lip and tongue palpation procedures were assessed for efficacy. The observation period for all safety and efficacy assessments was 2 hours. A safety review of blinded data was performed by the Medical Monitor of the study after 30 subjects had completed the study.

Documents

Study results

150322_OraVerse_USPaedStudy_CSR_final_summary.pdf(258.73 KB)

Data management

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