Plasma concentration of lidocaine and its metabolites after topical application of Lidocainedental gel 15% w/v to the oral mucosa

First published: 15/05/2025

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000582

EU PAS number

EUPAS1000000582

Study ID

1000000582

DARWIN EU® study

No

Study countries

Greece

Study description

Phase I pharmacokinetic study in 12 healthy volunteers.

Primary Objective: To determine the plasma levels of lidocaine and its two key metabolites, MEGX and GX,

after topical application of Lidocaine 15% w/v Dental Gel to the oral mucosa.

Secondary Objectives: To evaluate the single-dose pharmacokinetics (PK) of lidocaine and its two key

metabolites, MEGX and GX, after topical application of Lidocaine 15% w/v Dental

Gel to the oral mucosa.

Study status

Finalised

Research institutions and networks

Institutions

CLINICAL RESEARCH UNIT, SCHOOL OF MEDICINE, PAPAGEORGIOU GENERAL HOSPITAL, ARISTOTLE UNIVERSITY OF THESSALONIKI (CRU-AUSoM)

Greece

First published: 26/02/2024

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

GEORGIOS PAPAZISIS

Primary lead investigator

ORCID number:

0000-0003-1641-9095

Study timelines

Date when funding contract was signed

Actual: 31/05/2023

Study start date

Planned: 12/09/2023

Actual: 12/09/2023

Date of final study report

Actual: 21/02/2024

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

EU Trial No. 2022-003798-43

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Clinical trial

Data collection methods:

Primary data collection

Study Design

Clinical trial regulatory scope

Pre-authorisation clinical trial

Clinical trial phase

Human pharmacology (Phase I)

Clinical trial randomisation

Non-randomised clinical trial

Clinical trial types

Single-arm trial

Study drug and medical condition

Name of medicine, other

Lidocaine dental gel 15% w/v

Population studied

Short description of the study population

12 healthy volunteers

Age groups

All

In utero

Paediatric Population (< 18 years)

Neonate

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Data management

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown