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

Last updated: 15/05/2025

Study Finalised

Administrative details

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

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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

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Primary lead investigator

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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

Medicinal product name, other

Lidocaine dental gel 15% w/v

Population studied

Short description of the study population

12 healthy volunteers

Age groups

- **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

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.

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