

# 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

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### Study ID

1000000582

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### DARWIN EU® study

No

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### Study countries

 Greece

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### 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.

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## 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

**ORCID number:**

0000-0003-1641-9095

## Study timelines

**Date when funding contract was signed**

Actual: 31/05/2023

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**Study start date**

Planned: 12/09/2023

Actual: 12/09/2023

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**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

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**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

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**Study type:**

Clinical trial

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**Data collection methods:**

Primary data collection

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**Study Design**

## **Clinical trial regulatory scope**

Pre-authorisation clinical trial

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## **Clinical trial phase**

Human pharmacology (Phase I)

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## **Clinical trial randomisation**

Non-randomised clinical trial

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## **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

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## **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

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**Check completeness**

Yes

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown