A retrospective observational chart review study to evaluate the clinical effectiveness of treatment with zanamivir 10 mg/ml solution for infusion in a cohort of intensive care unit-treated (ICU) patients with complicated influenza infection (208165)

First published: 16/10/2020

Last updated: 07/04/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48211

EU PAS number

EUPAS37605

Study ID

48211

DARWIN EU® study

No

Study countries

☐ Netherlands

☐ United Kingdom

Study description

The study aims to gain an understanding of the clinical management of complicated influenza in ICUs in Europe and to investigate the clinical effectiveness of IV Zanamivir in the treatment of patients with complicated influenza in this setting.

Study status

Ongoing

Research institutions and networks

Institutions

OXON Epidemiology

☐ Spain

☐ United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

GSK Clinical Disclosure Advisor

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/07/2019

Actual: 25/07/2020

Study start date

Planned: 03/11/2020

Actual: 03/11/2020

Date of final study report

Planned: 23/01/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-208165-protocol-redact.pdf(1.81 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

Among ICU-admitted patients with complicated influenza, all-cause in-hospital mortality will be compared between patients who received IVZ treatment with a propensity score matched group of patients who did not receive this therapy during the same influenza season and/or pandemic(s).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

DECTOVA

Study drug International non-proprietary name (INN) or common name

ZANAMIVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AH01) zanamivir

zanamivir

Medical condition to be studied

Influenza

Population studied

Age groups

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)

Estimated number of subjects

1100

Study design details

Outcomes

The primary efficacy variable is defined as the length of time between the index date and all-cause in-hospital mortality. Patients who do not experience all-cause in-hospital mortality will be censored at 28 days post treatment/matching or at loss to follow up.

- All-cause in-hospital mortality up to end of follow-up (defined as 28 days post index date or at loss to follow-up)
- All-cause in-hospital mortality at Day 7, 10 and 14 after treatment initiation/matching
- Ordinal scale for clinical course of influenza disease at Day 7, 10 and 14 after

treatment initiation/matching

Data analysis plan

The primary analysis will consist of a matched cox regression model to estimate all-cause in-hospital mortality, presented as a hazard ratio for IV Zanamivir treatment vs matched control. A similar regression analysis will be performed to estimate in-hospital survival on day 7, 10 and 14 after treatment initiation/matching, and a proportional odds regression model will be fitted to analyse the ordinal scale date on the same days.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective Medical Chart Review

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