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: 13/05/2024

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 institution and networks

Institutions

OXON Epidemiology
Spain
United Kingdom
First published: 06/12/2010
Last updated
15/03/2024

Institution
Non-Pharmaceutical company
Laboratory/Research/Testing facility
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:

26/10/2020
Actual:
03/11/2020

Date of final study report
Planned:
30/01/2026

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 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
100000096431
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