

An Intravenous (IV) Zanamivir Pharmacokinetics (PK) Study in Hospitalized Neonates and Infants With Influenza Infection

NCT04494412

Status	RECRUITING
Phase	Phase 2
Sponsor	GlaxoSmithKline
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (6)

- Neonates and infants who are aged less than 6 months (corrected age) at the time of the informed consent signed by legally acceptable representative (LAR) of minors. Preterm neonates and infants will be eligible for inclusion but must have reached PMA of at least 28 weeks.
- Participants who are hospitalized with influenza infection, confirmed by a positive rapid molecular diagnostic test for influenza, or a local quantitative Reverse transcriptase-polymerase chain reaction (RT-PCR) test and who must have a potential for improvement. Participants with negative rapid molecular test result suspected of having influenza can be enrolled following confirmatory testing by quantitative RT-PCR.
- Participants with a high risk of altered oral drug absorption, represented by multi-organ dysfunction (dysfunction of at least 2 organs, as defined by the treating physician). (applicable only for Netherlands)
- Body weight ≥ 1 kilograms (kg).
- No gender restriction.

... and 1 more (see full listing online)

Exclusion (15)

- Participants who are known or suspected to be hypersensitive to any component of the study medication.
- Participants with a disease process which is likely to be irreversible.
- Liver function:
- Participants who meet the following criteria at Baseline:
- Alanine transaminase (ALT) ≥ 3 times upper limit of normal (ULN) with bilirubin ≥ 2 times ULN

... and 10 more (see full listing online)

Locations (9 total)

GSK Investigational Site, Florence, Italy
GSK Investigational Site, Messina, Italy
GSK Investigational Site, Milan, Italy

... and 6 more locations