

Safety and Effectiveness of Piperacillin/Tazobactam (Zosyn®) in the Treatment of Pediatric Hospital Acquired Pneumonia (HAP): A Retrospective Cohort Study

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Study

Finalised

Administrative details

EU PAS number

EUPAS8352

Study ID

50654

DARWIN EU® study

No

Study countries



United States

Study description

This is a retrospective cohort study to study the safety profile and effectiveness of Piperacillin/Tazobactam in pediatric patients treated for HAP. The study will utilize data from the Paediatric Health Information System (PHIS) database and medical charts.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

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Study contact

muhammad.younus2@pfizer.com

Primary lead investigator

Muhammad Younus

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/11/2013

Actual: 15/11/2013

Study start date

Planned: 02/03/2015

Actual: 02/03/2015

Date of final study report

Planned: 30/04/2019

Actual: 30/04/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

[Zosyn study B2361001 Protocol_EU PAS Register.pdf](#) (412.09 KB)

[Zosyn Pediatric HAP Study Protocol Amendment IV \(B2361001\) __EU PAS.pdf](#)
(834.18 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study is to assess safety and effectiveness of piperacillin/Tazobactam for the treatment of hospital acquired pneumonia (HAP) in pediatric patients.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Medicinal product name, other

Zosyn

Medical condition to be studied

Pneumonia

Population studied

Short description of the study population

The study population involved pediatric patients aged 2 months to <18 years diagnosed with hospital acquired pneumonia (HAP) received treatment with piperacillin/tazobactam identified from the Pediatric Health Information System

(PHIS) between January 01, 2003 and June 30, 2016.

Inclusion criteria:

- Hospital admission between January 1, 2003 and June 30, 2016,
- Aged between 2 months and 18 years at the time of hospital admission,
- Presence of at least one discharge ICD-9-CM code consistent with bacterial pneumonia (Table 1), and
- Received at least 1 dose of P/T or comparator HAP appropriate antibiotic during the hospitalization.

Exclusion criteria:

- Patients who have received an antibiotic(s) consistent with treatment of CAP (i.e., 2nd or 3rd Generation cephalosporins, ampicillin/amoxicillin, amoxicillin/clavulanic acid, ampicillin/sulbactam, azithromycin, clindamycin, or penicillin) during the first two days of hospitalization,
- Patients with a diagnosis of cystic fibrosis based on ICD-9 CM codes (Table 2); these patients will be excluded because they are frequently admitted for cystic fibrosis pulmonary exacerbations and receive similar antibiotic therapy but likely do not have HAP,
- Patients who were started on two HAP appropriate antibiotics simultaneously (within one day). These patients will be excluded because they will likely to be clinically different than patients started on monotherapy,
- Patients who received P/T or comparator antibiotics for other infection(s) prior to the diagnosis of HAP, or,
- Patients with missing pharmacy data in PHIS

Age groups

- Children (2 to < 12 years)
 - Adolescents (12 to < 18 years)
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Special population of interest

Other

Special population of interest, other

Hospital acquired pneumonia patients

Estimated number of subjects

450

Study design details

Outcomes

To estimate the risk of serious events including mortality among pediatric patients with HAP in the US, comparing Piperacillin/Tazobactam to comparator HAP appropriate antibiotics (i.e. ticarcillin-clavulanate, carbapenems, ceftazidime, cefepime, or ciprofloxacin). To evaluate effectiveness of the antibiotic therapy (using binary treatment outcome “patient clinically improved” or patient clinically did not improve”) in pediatric patients with HAP in the US, comparing Piperacillin/Tazobactam to comparator HAP appropriate antibiotic therapies.

Data analysis plan

Descriptive statistics will be performed to describe patient characteristics such as age, sex, race/ethnicity, geographical location, length of hospital stay, presence of co-morbid conditions at the time of hospital admission, concomitant medication use and ventilator support in the P/T exposed and comparator groups. For each of the serious events outcomes, one or more events that occur during the follow-up time will be counted for each patient. Each outcome will be analyzed using a Poisson model with an offset for person-time at risk and robust variance estimate. Results will be presented by group (P/T, comparator) for

the: • Total number of events, • Cumulative person-time at risk, • Model adjusted event rate per 1,000 person years with corresponding 95% CI, and • Model adjusted incidence rate ratio (IRR) with corresponding 95% CI.

Documents

Study results

[B2361001 \(Formerly 0910K2-4015\) Non-Interventional Study Report Abstract EU PAS Register.pdf](#) (244.3 KB)

Study report

[B2361001 Full Study Report_EU PAS Register.pdf](#) (673.67 KB)

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.

Data sources

Data source(s), other

Pediatric Health Information System (PHIS) United States

Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

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