NON-INTERVENTIONAL POST-AUTHORIZATION SAFETY STUDY TO DESCRIBE USE BY INDICATION AND CLINICAL OUTCOMES AMONG PATIENTS WITH COMPLICATED INTRA-ABDOMINAL INFECTION OR COMPLICATED SKIN AND SOFT TISSUE INFECTION TREATED WITH TIGECYCLINE (TYGACIL®) IN THE EUROPEAN UNION

First published: 18/03/2013

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS3674

Study ID

15651

DARWIN EU® study

No

Study countries

Austria

Germany

Greece

Italy

United Kingdom

Study description

Background: Tygacil is an intravenously administered antibiotic indicated in the EU for treatment of complicated intra-abdominal infection (cIAI) and complicated skin or soft tissue infection (cSSTI) excluding diabetic foot infection. This retrospective medical record review study will evaluate the effectiveness of 2011 Risk Minimization Measures (RMM) aimed at reducing off-label use of Tygacil in the EU by assessing the proportion of off-label use before and after RMM implementation. Objectives: 1) Examine the distribution of indications for Tygacil use in the EU before and after RMM implementation, 2) Determine the incidence of superinfection and lack of efficacy among adult patients treated with Tygacil for cSSTI and cIAI in the EU before and after RMM implementation.Data Collection:All patients treated with Tygacil for any indication during the study period will be retrospectively identified at participating centers in 3-6 of the top-prescribing EU countries. Patient medical records will be reviewed to determine indication for Tygacil use and to identify potential superinfection and lack of efficacy cases among those treated for approved indications. A committee of external adjudicators will review all relevant medical record data from these potential cases to determine their actual status. Methods:Frequencies of indications and the proportion of off-label use of Tygacil will be calculated before and after RMM implementation. The

incidence of superinfection and lack of efficacy will be calculated in pre- and post-RMM periods among adult patients treated for cIAI and cSSTI. A descriptive analysis of pathogens associated with infection treated with Tygacil will be performed where microbiology data are available. An exploratory, hypothesis-generating multivariate comparative analysis will also be conducted to assess any change in superinfection and lack of efficacy between the pre- and post-RMM implementation period among on-label Tygacil users.

Study status

Finalised

Research institutions and networks

Institutions

Scientific Affairs, Outcome SARL

Switzerland

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Institution | Other

Multiple centres: 13 centres are involved in the study

Contact details

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Study contact

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Primary lead investigator

Veronica Frajzyngier

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/01/2013

Actual: 04/01/2013

Study start date

Planned: 10/06/2013

Actual: 23/05/2013

Date of interim report, if expected

Planned: 31/01/2014

Date of final study report

Planned: 30/09/2014

Actual: 16/09/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B1811184 Protocol Amendment 2 08 November 2012.pdf (527.72 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to assess the effectiveness of recently implemented Tygacil Risk Minimization Measures (RMM) by describing indications for Tygacil use, and to describe clinical outcomes among adult patients with cIAI or cSSTI treated with approved doses of Tygacil in the EU before and after implementation of the RMM.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TYGACIL

Medical condition to be studied

Skin infection

Abdominal infection

Population studied

Short description of the study population

Patients with complicated intra-abdominal infection or complicated skin and soft tissue infection treated with Tygacil at any dose and for any indication within selected hospitals or wards between February 2010 and February 2011 and between February 2012 and February 2013.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with Intra-abdominal infection (cIAI) and complicated skin or soft tissue infection (cSSTI)

Estimated number of subjects

600

Study design details

Outcomes

1) Indication for Tygacil use defined as the infection type which Tygacil is prescribed to treat, 2) Superinfection and lack of efficacy throughout the duration of Tygacil treatment at approved doses for approved indications. Pathogen associated with the infection for which Tygacil was prescribed to treat.

Data analysis plan

Indication for Use: Distribution of indications for Tygacil will be analyzed overall and stratified by study period (pre- vs. post-RMM). Proportion of off-label use and its 95% confidence interval (CI) will be estimated for pre- and post-RMM periods. Off- and on-label users of Tygacil will be described in terms of patient characteristics (demographics, comorbidities, prior antibiotic therapy and surgical procedures, etc.) and treatment characteristics (Tygacil monotherapy vs. combination therapy, dose, duration of treatment, etc.). No Statistical inferences will be made.Superinfection and Lack of Efficacy: Incidence proportions and associated 95% CI for superinfection and lack of efficacy will be estimated separately for patients treated with approved doses of Tygacil for cIAI and cSSTI. Incidence estimates will be stratified as data allows by disease severity, Tygacil monotherapy or combination therapy, Tygacil duration, and other potential confounding factors.

Documents

Study results

b1811184-abstract_disclosed.pdf (1 MB)

B1811184_STUDYREPORT_FINAL_16SEP2014_disclose_Redacted.pdf (590.99 KB)

Study report

B1811184_STUDYREPORT_FINAL_16SEP2014_disclose part 2.pdf (464.63 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 sources (types)

Other

Data sources (types), other

Retrospective medical charts review study

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

Unknown