Clinical trial results:
Eficacia y seguridad de Piperacilina/Tazobactam administrada en perfusión continua versus infusión intermitente en pacientes con infección complicada o nosocomial con sospecha o aislamiento de Pseudomonas aeruginosa.

Summary

EudraCT number	2010-024606-34
Trial protocol	ES
Global end of trial date	10 September 2014

Results information

Result version number	v1 (current)
This version publication date	26 March 2021
First version publication date	26 March 2021
Summary attachment (see zip file)	Final analysis of results (Informe final EECC Pipertazo firmado.pdf)

Trial information

Trial identification

Sponsor protocol code	PiperTazo

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundación Pública Andaluza Progreso y Salud
Sponsor organisation address	Parque Científico y Tecnológico Cartuja, Avda. Américo Vespucio, 15. Edificio S-2. 41092 Sevilla, Seville, Spain, 41092
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 September 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 September 2014
Global end of trial reached?	Yes
Global end of trial date	10 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

verificar, que la administración de piperacilina/tazobactam en perfusión continua administrada para tratar infecciones complicadas o de origen nosocomial con sospecha o aislamiento de Pseudomonas aeruginosa es, superior en eficacia a una dosis un 30% superior administrada en infusión corta convencional.

Protection of trial subjects:

The sponsor undertakes to ensure safety and to promptly report any information that could modify the risk/benefit ratio of piperacillin/tazobactam, or determine changes in the schedule of administration or conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 August 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 78
Worldwide total number of subjects	78
EEA total number of subjects	78

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	78

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Once the patient is eligible, meets the inclusion criteria, does not meet any exclusion criteria and signs the informed consent to participate in the clinical trial, randomisation will proceed.

Pre-assignment

Screening details:

Once the patient is eligible, meets the inclusion criteria, does not meet any exclusion criteria and signs the informed consent to participate in the clinical trial, randomisation will proceed.

Period 1

Period 1 title	Recruitment and follow-up
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Continuous perfusion

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Piperacillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Other use

Dosage and administration details:

Initial dose of 2 of Piperacillin + 24-hour continuous infusion of 8 g Piperacillin in 500 mi of saline (NaCI 0.9%).

Investigational medicinal product name	Tazobactam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Other use

Dosage and administration details:

Initial dose of 0.25 g of Tazobactam + 24-hour continuous infusion of 1 g Tazobactam in 500 mi of saline (NaCI 0.9%).

Arm title	Intermittent perfusion

Arm description: -

Arm type	Control
Investigational medicinal product name	Piperacillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Other use

Dosage and administration details:

4 g/100 mi of Piperacillin every 8 hours as a short infusion.

Investigational medicinal product name	Tazobactam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Other use

Dosage and administration details:

0.5 g/100 mi of Tazobactam every 8 hours as a short infusion.

Number of subjects in period 1	Continuous perfusion	Intermittent perfusion
Started	40	38
Completed	40	38

Period 2

Period 2 title	Data analysis
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Continuous perfusion

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Piperacillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Other use

Dosage and administration details:

Initial dose of 2 of Piperacillin + 24-hour continuous infusion of 8 g Piperacillin in 500 mi of saline (NaCI 0.9%).

Investigational medicinal product name	Tazobactam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Other use

Dosage and administration details:

Initial dose of 0.25 g of Tazobactam + 24-hour continuous infusion of 1 g Tazobactam in 500 mi of saline (NaCI 0.9%).

Arm title	Intermittent perfusion

Arm description: -

Arm type	Control

Investigational medicinal product name	Piperacillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Other use

Dosage and administration details:

4 g/100 mi of Piperacillin every 8 hours as a short infusion.

Investigational medicinal product name	Tazobactam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Other use

Dosage and administration details:

0.5 g/100 mi of Tazobactam every 8 hours as a short infusion.

Number of subjects in period 2	Continuous perfusion	Intermittent perfusion
Started	40	38
Completed	40	38

Baseline characteristics

Reporting groups	
Reporting group title	Continuous perfusion
Reporting group description: -	
Reporting group title	Intermittent perfusion
Reporting group description: -	

Reporting group values	Continuous perfusion	Intermittent perfusion	Total
Number of subjects	40	38	78
Age categorical Units: Subjects			
18 years and over	40	38	78
Age continuous Units: years			
arithmetic mean	64.30	63.80	
standard deviation	± 14.25	± 17.25	-
Gender categorical Units: Subjects			
Female	16	16	32
Male	24	22	46
Height Units: Metres			
arithmetic mean	1.66	1.63	
standard deviation	± 0.10	± 0.12	-
Weight Units: Kg			
arithmetic mean	74.34	76.14	
standard deviation	± 15.83	± 15.90	-

End points

End points reporting groups

Reporting group title	Continuous perfusion
Reporting group description: -	
Reporting group title	Intermittent perfusion
Reporting group description: -	
Reporting group title	Continuous perfusion
Reporting group description: -	
Reporting group title	Intermittent perfusion
Reporting group description: -	

Primary: Clinical response at the end of treatment

End point title	Clinical response at the end of treatment[1]
End point description:	
End point type	Primary
End point timeframe:	
Throughout the study	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Information is not available for some of the required fields. However, the final analysis of the results is attached where all the information of the statistical analysis appears.

End point values	Continuous perfusion	Intermittent perfusion		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	38		
Units: Participants				
healing	31	27		
failure	7	13		

Statistical analyses

No statistical analyses for this end point

Primary: treatment time to cure

End point title	treatment time to cure[2]
End point description:	
End point type	Primary
End point timeframe:	
During the study	

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Information is not available for some of the required fields. However, the final analysis of the results is attached where all the information of the statistical analysis appears.

End point values	Continuous perfusion	Intermittent perfusion		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	38		
Units: Days				
arithmetic mean (standard deviation)	9.62 (± 0.64)	7.55 (± 0.76)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

During the study

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Both groups

Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No non-serious adverse effects have been reported.

Serious adverse events	Both groups		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 78 (3.85%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Blood and lymphatic system disorders			
febrile neutropenia			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
pancreatic neoplasm leading to death			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 4 %

Non-serious adverse events	Both groups		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 78 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported