Clinical trial results:
Efficacy of short duration sequential therapy versus standard intravenous therapy for patients with uncomplicated catheter related bacteremia due to S. aureus methicillin-susceptible.

Summary

EudraCT number	2013-000511-24
Trial protocol	ES
Global end of trial date	10 September 2015

Results information

Result version number	v1 (current)
This version publication date	01 April 2021
First version publication date	01 April 2021
Summary attachment (see zip file)	Final report of results (Informe_Final_FPS_COL-2013-06_Fdo.pdf)

Trial information

Trial identification

Sponsor protocol code	FPS-COL-2013-06

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
Public contact	Maria del Mar Benjumea Vargas, FUNDACIÓN PÚBLICA ANDALUZA PROGRESO Y SALUD, 0034 955040460, maria.benjumea@juntadeandalucia.es
Scientific contact	Maria del Mar Benjumea Vargas, FUNDACIÓN PÚBLICA ANDALUZA PROGRESO Y SALUD, 0034 955040460, maria.benjumea@juntadeandalucia.es

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 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 September 2015
Global end of trial reached?	Yes
Global end of trial date	10 September 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Assess the eficacy of a sequential regimen of 14 days in patients with catheter-related bacteremia by S. aureus methicillin susceptible, selected based on a set of pre-established criteria equals the pattern of the conventional intravenous

Protection of trial subjects:

This trial should be conducted in accordance with the protocol following the sponsor's SOPs. The trial shall be conducted in accordance with the recommendations for Clinical Trials and Investigational Product Evaluation in Man, as contained in the Declaration of Helsinki, as revised at successive World Assemblies (WMA, 2008), and the current Spanish Clinical Trial Legislation (RD 223/2004). The ICH-GCP standards (CPMP/ICH/135/95) will be followed.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	01 April 2013
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: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients with uncomplicated catheter-associated bacteraemia due to methicillin-sensitive S. aureus, ≥ 18 years with a minimum weight of 40 kg.

Pre-assignment

Screening details:

Patients with uncomplicated catheter-associated bacteraemia due to methicillin-sensitive S. aureus, ≥ 18 years with a minimum weight of 40 kg.

Period 1

Period 1 title	Recruitment and follw-up
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Experimental

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Levofloxacino
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Compressed lozenge
Routes of administration	Oral use

Dosage and administration details:

cloxacillin 2g/4 hours i.v., 5 days followed by levofloxacin 500 mg v.o. /24h, 9 days.

Investigational medicinal product name	Cloxacillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

cloxacillin 2g/4 hours i.v., 5 days followed by levofloxacin 500 mg v.o. /24h, 9 days.

Number of subjects in period 1	Experimental
Started	1
Completed	1

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

Arms

Arm title	Experimental
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Levofloxacino
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Compressed lozenge
Routes of administration	Oral use
Dosage and administration details: cloxacillin 2g/4 hours i.v., 5 days followed by levofloxacin 500 mg v.o. /24h, 9 days.	
Investigational medicinal product name	Cloxacillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intravenous use
Dosage and administration details: cloxacillin 2g/4 hours i.v., 5 days followed by levofloxacin 500 mg v.o. /24h, 9 days.	

Number of subjects in period 2	Experimental
Started	1
Completed	1

Baseline characteristics

Reporting groups	
Reporting group title	Recruitment and follw-up
Reporting group description:	
Only one patient was recruited in the clinical trial	

Reporting group values	Recruitment and follw-up	Total	
Number of subjects	1	1	
Age categorical Units: Subjects			
Adults (18-64 years)	1	1	
Age continuous Units: years			
arithmetic mean	49		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	1	1	

End points

End points reporting groups

Reporting group title	Experimental
Reporting group description: -	
Reporting group title	Experimental
Reporting group description: -	

Primary: Failure rate

End point title	Failure rate[1]
End point description:	
End point type	Primary
End point timeframe:	
During 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: Only one patient was enrolled in this clinical trial. Statistical analysis could not be performed due to insufficient data.

End point values	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: death or complications				
no death or complications	1			

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

Reporting groups	
Reporting group title	Experimental
Reporting group description: -	

Serious adverse events	Experimental		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Experimental		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		

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 adverse events were reported in the only clinical trial participant.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 July 2013	Change in the number of visits during the trial, in addition to the elimination of one site that did not receive a favourable opinion from its local committee, and the separation of two annexes from the protocol because they were considered independent documents.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Only one patient was enrolled in the clinical trial and therefore, results could not be achieved.

Notes: