Clinical trial results:
Concentración y actividad antibiótica en soluciones de sellado

Summary

EudraCT number	2010-023814-29
Trial protocol	ES
Global end of trial date	28 January 2015

Results information

Result version number	v1 (current)
This version publication date	26 November 2021
First version publication date	26 November 2021
Summary attachment (see zip file)	Final report summary (CASS110775 informe final.pdf)

Trial information

Trial identification

Sponsor protocol code	CAS110775 (CONAN)

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Clínica Universidad de Navarra
Sponsor organisation address	Avda. Pío XII, 36, Pamplona, Spain, 31008
Public contact	UCEC, Clínica Universidad de Navarra - UCEC, 34 948255 400, ucicec@unav.es
Scientific contact	UCEC, Clínica Universidad de Navarra - UCEC, 34 948255 400, ucicec@unav.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	28 January 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 January 2015
Global end of trial reached?	Yes
Global end of trial date	28 January 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Conocer a lo largo del tiempo la concentración de Vancomicina, Teicoplanina, Linezolid, Daptomicina y Tigeciclina en soluciones de sellado aplicados in vivo

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 December 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: 93
Worldwide total number of subjects	93
EEA total number of subjects	93

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)	63
From 65 to 84 years	30
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Over a study period of 32 months, a total of 484 consecutive patients were assessed for eligibility (Figure 1). By the end of the study, a total of ninety-three patients have been randomized to the ALS groups

Pre-assignment

Screening details:

Over a study period of 32 months, a total of 484 consecutive patients were assessed for eligibility (Figure 1). By the end of the study, a total of ninety-three patients have been randomized to the ALS groups

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	ALS group vancomycin

Arm description:

Eleven patients to receive vancomycin

Arm type	Experimental
Investigational medicinal product name	vancomycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pharmaceutical dose form not applicable
Routes of administration	Route of administration not applicable

Dosage and administration details:

The antimicrobial lock technique (ALT) consists of the infusion of a highly concentrated antimicrobial solution into the catheter lumen to achieve the eradication of microorganisms.
ALS groups: Eleven patients to receive vancomycin, twenty-four patients to teicoplanin, ten patients to linezolid, twenty-six patients to daptomycin, and twenty-two patients to receive tigecycline.
All lock solutions were composed by heparin and an antimicrobial to achieve a concentration of vancomycin 2 mg/ml, teicoplanin 10 mg/ml, linezolid 1.8 mg/ml, daptomycin 5 mg/ml, and tigecycline 4.5 mg/ml.

Arm title	ALS group teicoplanin

Arm description:

twenty-four patients to teicoplanin

Arm type	Experimental
Investigational medicinal product name	teicoplanin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pharmaceutical dose form not applicable
Routes of administration	Route of administration not applicable

Dosage and administration details:

The antimicrobial lock technique (ALT) consists of the infusion of a highly concentrated antimicrobial solution into the catheter lumen to achieve the eradication of microorganisms.
ALS groups: Eleven patients to receive vancomycin, twenty-four patients to teicoplanin, ten patients to linezolid, twenty-six patients to daptomycin, and twenty-two patients to receive tigecycline.
All lock solutions were composed by heparin and an antimicrobial to achieve a concentration of vancomycin 2 mg/ml, teicoplanin 10 mg/ml, linezolid 1.8 mg/ml, daptomycin 5 mg/ml, and tigecycline 4.5 mg/ml.

Arm title	ALS group linezolid

Arm description:

ten patients to linezolid

Arm type	Experimental
Investigational medicinal product name	linezolidrr
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pharmaceutical dose form not applicable
Routes of administration	Route of administration not applicable

Dosage and administration details:

The antimicrobial lock technique (ALT) consists of the infusion of a highly concentrated antimicrobial solution into the catheter lumen to achieve the eradication of microorganisms.
ALS groups: Eleven patients to receive vancomycin, twenty-four patients to teicoplanin, ten patients to linezolid, twenty-six patients to daptomycin, and twenty-two patients to receive tigecycline.
All lock solutions were composed by heparin and an antimicrobial to achieve a concentration of vancomycin 2 mg/ml, teicoplanin 10 mg/ml, linezolid 1.8 mg/ml, daptomycin 5 mg/ml, and tigecycline 4.5 mg/ml.

Arm title	ALS group daptomycin

Arm description:

twenty-six patients to daptomycin

Arm type	Experimental
Investigational medicinal product name	daptomycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pharmaceutical dose form not applicable
Routes of administration	Route of administration not applicable

Dosage and administration details:

The antimicrobial lock technique (ALT) consists of the infusion of a highly concentrated antimicrobial solution into the catheter lumen to achieve the eradication of microorganisms.
ALS groups: Eleven patients to receive vancomycin, twenty-four patients to teicoplanin, ten patients to linezolid, twenty-six patients to daptomycin, and twenty-two patients to receive tigecycline.
All lock solutions were composed by heparin and an antimicrobial to achieve a concentration of vancomycin 2 mg/ml, teicoplanin 10 mg/ml, linezolid 1.8 mg/ml, daptomycin 5 mg/ml, and tigecycline 4.5 mg/ml.

Arm title	ALS group tigecycline

Arm description:

twenty-two patients to receive tigecycline

Arm type	Experimental
Investigational medicinal product name	tigecycline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pharmaceutical dose form not applicable
Routes of administration	Route of administration not applicable

Dosage and administration details:

The antimicrobial lock technique (ALT) consists of the infusion of a highly concentrated antimicrobial solution into the catheter lumen to achieve the eradication of microorganisms.
ALS groups: Eleven patients to receive vancomycin, twenty-four patients to teicoplanin, ten patients to linezolid, twenty-six patients to daptomycin, and twenty-two patients to receive tigecycline.
All lock solutions were composed by heparin and an antimicrobial to achieve a concentration of vancomycin 2 mg/ml, teicoplanin 10 mg/ml, linezolid 1.8 mg/ml, daptomycin 5 mg/ml, and tigecycline 4.5 mg/ml.

Number of subjects in period 1	ALS group vancomycin	ALS group teicoplanin	ALS group linezolid
Started	11	24	10
Completed	11	24	10

Number of subjects in period 1	ALS group daptomycin	ALS group tigecycline
Started	26	22
Completed	26	22

Baseline characteristics

End points

End points reporting groups	
Reporting group title	ALS group vancomycin
Reporting group description: Eleven patients to receive vancomycin	
Reporting group title	ALS group teicoplanin
Reporting group description: twenty-four patients to teicoplanin	
Reporting group title	ALS group linezolid
Reporting group description: ten patients to linezolid	
Reporting group title	ALS group daptomycin
Reporting group description: twenty-six patients to daptomycin	
Reporting group title	ALS group tigecycline
Reporting group description: twenty-two patients to receive tigecycline	

Primary: Time when the intraluminal concentration decreased below 1 mg/ml

End point title	Time when the intraluminal concentration decreased below 1 mg/ml[1]
End point description: The treatment of each patient will last between 1 and 10 days.	
End point type	Primary
End point timeframe: 10 days	

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: The Kruskal-Wallis test was used to compare the antimicrobial concentrations among the groups. The Wilcoxon test was used to compare the antimicrobial concentrations at the end of dwelling time with the concentrations administered. Statistical significance was established at an alpha value of . 05. All P values were two-tailed. The statistical analyses were performed using SPSS version 15.0.1 software (SPSS Inc., Chicago, IL, USA).

End point values	ALS group vancomycin	ALS group teicoplanin	ALS group linezolid	ALS group daptomycin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	24	10	26
Units: Days				
number (not applicable)	11	24	10	26

End point values	ALS group tigecycline			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: Days				

number (not applicable)	22			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

AAs will be collected from the moment the patient signs the Informed Consent (IC) until 3 days after the administration of the last dose of the investigational drug and / or the last visit.

Assessment type	Systematic

Dictionary used

Dictionary name	NA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 1 %

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: The information will be updated as soon as available

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 February 2012	Protocol changes (concentrations, safety assessment, visit schedule)
05 July 2012	Change of sponsor
04 September 2012	Changes in inclusion criteria
26 March 2013	Change of the person pharmacovigilance responsible and other relevant protocol changes such as replacement criteria and changes with samples
27 October 2014	suspension of the tigecycline treatment arm

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported