Clinical trial results:
Do use of torniquete reduce the impact of the antibiotic treatment during orthopedic treatment?

Summary

EudraCT number	2018-000217-21
Trial protocol	DK
Global end of trial date	29 November 2019

Results information

Result version number	v1 (current)
This version publication date	08 February 2021
First version publication date	08 February 2021

Trial information

Trial identification

Sponsor protocol code	310816

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle juul-jensens boulevard 99, Aarhus N, Denmark, 8200
Public contact	Pelle Hanberg, Horsens Regional Hospital, 0045 28744852, pellehanberg@clin.au.dk
Scientific contact	Pelle Hanberg, Horsens Regional Hospital, 0045 28744852, pellehanberg@clin.au.dk

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	30 September 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 November 2019
Global end of trial reached?	Yes
Global end of trial date	29 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objectives of this trial is to asses the penetration of cefuroxime into muscle, subcutaneous and bone tissue using the pharmacokinetic tool microdialysis, and to see how the use of torniquete affects the penetration and the ischaemic markers. The primary endpoints are the time for which the cefuroxime concentration is maintained above the minimal inhibitory concentration (T>MIC), penetrations ratios and the iscaemic markers. Secondary endpoints are standard pharmacokinetic parameters (eg. half-life, Cmax, Tmax and AUC).

Protection of trial subjects:

No patients experience any discomforts with the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	7
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

medical evaluation

Pre-assignment

Screening details:

In- and excluding criteria has to be fulfilled before assignment to the study

Period 1

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

Arms

Arm title	over all

Arm description:

All subjects received 1500 mg cefuroxime x 2 with an 6 hours interval.

Arm type	All subjects recieved the same amount of drug
Investigational medicinal product name	Cefuroxime
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1500 mg x 2 given intravenously over 10 min

Number of subjects in period 1	over all
Started	10
Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	overall trial (overall period)

Reporting group description: -

Reporting group values	overall trial (overall period)	Total	
Number of subjects	10	10	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	7	7	
From 65-84 years	3	3	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	7	7	
Male	3	3	

End points

End points reporting groups

Reporting group title	over all

Reporting group description:

All subjects received 1500 mg cefuroxime x 2 with an 6 hours interval.

Primary: T>MIC (4 microgram/ml)

End point title	T>MIC (4 microgram/ml)[1]

End point description:

The time with concentrations above the minimal inhibitory concentration (T>MIC) (4 µg/mL) in min for plasma, subcutaneous tissue, skeletal muscle, and calcaneal cancellous bone on both the tourniquet and non-tourniquet leg from time 0-6 h

End point type	Primary

End point timeframe:

0-6 h of sampling

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: Please find "T>MIC (4 microgram/ml)"

End point values	over all			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: minute				
arithmetic mean (confidence interval 95%)	0 (0 to 0)			

Attachments (see zip file)	T>MIC (4 microgram/ml)/T>MIC 4.pdf

Statistical analyses

No statistical analyses for this end point

Primary: ischemic metabolites ratio

End point title	ischemic metabolites ratio[2]

End point description:

The mean concentration difference (%) of ischemic metabolites between the tourniquet-exposed and non-tourniquet-exposed leg (tourniquet/non-tourniquet).

End point type	Primary

End point timeframe:

0-12 h from sampling

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: Please find "ischemic metabolites ratio"

End point values	over all			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: percent				
arithmetic mean (confidence interval 95%)	0 (0 to 0)			

Attachments (see zip file)	ischemic metabolites ratio/ischemic metabolites ratio.pdf

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: from placement of the microdialysis catheter until the last collected blood sample.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	produktresume
Dictionary version	21. marts

Frequency threshold for reporting non-serious adverse events: 0 %

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.

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