EU Clinical Trials Register

Clinical trial results:
Pharmacokinetics of ciprofloxacine in pediatric patients, a pilot study – SAFE PEDRUG

EudraCT number	2014-004638-24
Trial protocol	BE
Global end of trial date	17 March 2017

Result version number	v1 (current)
This version publication date	03 April 2022
First version publication date	03 April 2022

Sponsor protocol code	SafePed01

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02598362
WHO universal trial number (UTN)	-

Notes:

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	C. Heymanslaan 10, 9000, Belgium, Ghent
Public contact	HIRUZ CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be

Notes:

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:

Analysis stage	Final
Date of interim/final analysis	06 September 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 March 2017
Global end of trial reached?	Yes
Global end of trial date	17 March 2017
Was the trial ended prematurely?	No

Notes:

Main objective of the trial:

Investigating the feasibility of a study method for pharmacokinetics (with emphasis on renal clearance) of ciprofloxacin in children.

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 May 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Country: Number of subjects enrolled	Belgium: 23
Worldwide total number of subjects	23
EEA total number of subjects	23

Notes:

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	3
Children (2-11 years)	10
Adolescents (12-17 years)	10
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Recruitment details:

23 patients were included starting from 28-May-2015. End of trial notification was dated 17-Mar-2018 (last patient last visit) and submitted to EC and CA on 28/08/2018.

Screening details:

fUTI group (UZ Brussels): patients aged 3 months-17years with rectal temperature of 38.5°C and significant leucocyturia or a positive urine nitrite test in a sterile urine sample and confirmed by culture. Profylaxis group (UZ Ghent): patients until age of 17years who use cipro for preventing urinary tract infectons.

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

Are arms mutually exclusive?	Yes
	fUTI arm (IV arm)

Arm description:

UZ Brussels patients aged 3 months-17years with rectal temperature of 38.5°C and significant leucocyturia or a positive urine nitrite test in a sterile urine sample and confirmed by culture.

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

Dosage and administration details:

15mg/kg twice daily

	Profylaxis arm (oral arm)

Arm description:

UZ Ghent patients until age of 17years who use cipro for preventing urinary tract infectons.
Oral administration

Arm type	Active comparator
Investigational medicinal product name	Ciprofloxacin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Normal dose (usual 10mg/kg daily)

	fUTI arm (IV arm)	Profylaxis arm (oral arm)
Started	10	13
Completed	10	13

Reporting group title	fUTI arm (IV arm)
Reporting group description:	
UZ Brussels patients aged 3 months-17years with rectal temperature of 38.5°C and significant leucocyturia or a positive urine nitrite test in a sterile urine sample and confirmed by culture.	
Reporting group title	Profylaxis arm (oral arm)
Reporting group description:	
UZ Ghent patients until age of 17years who use cipro for preventing urinary tract infectons. Oral administration	

	fUTI arm (IV arm)	Profylaxis arm (oral arm)	Total
Number of subjects	10	13	23
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
median	9.86	6.43	
full range (min-max)	0.51 to 15.5	0.31 to 15.4	-
Gender categorical Units: Subjects			
Female	8	6	14
Male	2	7	9
Diagnose Units: Subjects			
Acute pyelonephritis	9	9	18
Cystitis	1	2	3
recurrent lower UTI	0	2	2
Comorbidities Units: Subjects			
CAKUT	3	7	10
Neurogenic bladder	1	0	1
BBD	2	1	3
CAKUT and stone disease	1	1	2
CAKUT and renal insufficiency	0	1	1
CAKUT and BBD	0	1	1
stone disease	0	1	1
None	3	1	4

Urine culture Units: Subjects			
Escherichia coli	4	5	9
Pseudomonas aeruginosa	3	4	7
Klebsiella pneumoniae	1	1	2
Proteus strains	0	1	1
No growth	2	2	4
Weight Units: kg			
median	26.7	18.3	
full range (min-max)	8.21 to 75.30	6.47 to 106	-
Serum cystatin C Units: mg/l			
median	0.71	0.86	
full range (min-max)	0.63 to 0.84	0.61 to 2.88	-
Serum creatinine Units: mg/dl			
median	0.49	0.64	
full range (min-max)	0.28 to 0.81	0.38 to 1.54	-
Kidney function Units: ml/min/1.73m²			
median	98.4	65.5	
full range (min-max)	73.7 to 116	6.75 to 84.6	-

	End group			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: l/kg				
median (full range (min-max))	0.55 (0.06 to 2.88)			

No statistical analyses for this end point

End point title	Bioavailibility

End point description:

End point type	Secondary

End point timeframe:
From start until end study

	End group			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: percentage				
number (not applicable)	59.6			

No statistical analyses for this end point

End point title	absorption

End point description:

End point type	Secondary

End point timeframe:
From start until end study

	End group			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: per hour				
number (not applicable)	0.596			

No statistical analyses for this end point

Timeframe for reporting adverse events:	
Adverse events will be reported between the first dose administration of trial medication and the last trial related activity	
Assessment type	Non-systematic

Dictionary name	MedDRA
Dictionary version	21.1

Reporting group title	fUTI arm (IV arm)
Reporting group description:	
UZ Brussels patients aged 3 months-17years with rectal temperature of 38.5°C and significant leucocyturia or a positive urine nitrite test in a sterile urine sample and confirmed by culture.	
Reporting group title	Profylaxis arm (oral arm)
Reporting group description:	
UZ Ghent patients until age of 17years who use cipro for preventing urinary tract infectons. Oral administration	

	fUTI arm (IV arm)	Profylaxis arm (oral arm)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 5 %

	fUTI arm (IV arm)	Profylaxis arm (oral arm)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (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 have been collected

Were there any global substantial amendments to the protocol? No

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Were there any global interruptions to the trial? No

None reported

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http://www.ncbi.nlm.nih.gov/pubmed/29987142