



Clinical trial results:

Colistin use in Cystic Fibrosis patients: pharmacokinetic studies (intravenous administration) in relation with pharmacodynamics, tolerance profile and risk of selection of resistance.

Summary

EudraCT number	2013-004987-80
Trial protocol	BE
Global end of trial date	04 May 2020

Results information

Result version number	v1 (current)
This version publication date	17 September 2025
First version publication date	17 September 2025
Summary attachment (see zip file)	2013-004987-80_results (2013-004987-80 - results - Standard doses of intravenous colistin do not achieve therapeutic plasma target levels in adult c.pdf)

Trial information

Trial identification

Sponsor protocol code	2013-Colistin
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	HUB - Hôpital Erasme
Sponsor organisation address	Route de Lennik 808, Brussels, Belgium,
Public contact	Dr Wellemans Isabelle, HUB - Hôpital Erasme, 0032 25558111, isabelle.wellemans@erasme.ulb.ac.be
Scientific contact	Dr Wellemans Isabelle, HUB- Hôpital Erasme, 0032 25558111, isabelle.wellemans@erasme.ulb.ac.be

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	04 May 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	04 May 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- 1) Prospectively evaluating the pharmacokinetics and pharmacodynamics of colistin in adult CF patients infected by multidrug resistant *P. aeruginosa* in order to propose algorithms for optimizing doses in this patients' population
- 2) Studying in vitro the pharmacodynamics of colistin activity against clinical isolates from the same patients when grown as biofilms as well as the conditions of drug exposure favoring selection of resistance in vitro.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 February 2014
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	Belgium: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment in Belgium. February 2014 - May 2020

Pre-assignment

Screening details:

We, prospectively, evaluated the pharmacokinetic (PK) profile of intra-venous (iv) colistin as well as its safety in adult CF patients presenting an acute exacerbation and colonized with Pa.

Period 1

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

Blinding implementation details:

The blinding was not applicable to the period

Arms

Arm title	CMS Therapy
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Colistin
Investigational medicinal product code	
Other name	Colistimethate Sodium
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Colistin was administered as a solution for infusion at a dose of 2 million units every 8 hours.

Number of subjects in period 1	CMS Therapy
Started	24
Completed	17
Not completed	7
Incomplete pharmacokinetic data collection for the	7

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	24	24	
Age categorical			
Units: Subjects			
Adults (18-64 years)	24	24	
Age continuous			
Units: years			
median	34.5		
full range (min-max)	20 to 57	-	
Gender categorical			
Units: Subjects			
Female	14	14	
Male	10	10	

End points

End points reporting groups

Reporting group title	CMS Therapy
Reporting group description: -	

Primary: Pharmacocinetic Colistine

End point title	Pharmacocinetic Colistine ^[1]
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End point description:

Cmax for CMS. We included 24 patients [14 F, median age (min-max) 34.5 yrs (20–57), body weight 57 kg (40–69), serum creatinine 0.7 mg/dL (0.47– 1.1)]. PK data are at present available from 17 patients. Cmax for CMS was 10.4 (8.4–12.4) mg/L, for total colistin A+B 1.97 (1.31–2.55) mg/L and for unbound colistin A+B 0.55 (0.37–0.69) mg/L. At trough level, all total colistin results (0.48 [0.25–0.67] mg/L) and unbound colistin (0.05 [0.03–0.09] mg/L) were inferior to the MIC of isolated strains and protein binding of colistin was high 87.5 (83.7–90.1) %.

End point type	Primary
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End point timeframe:

End of Trial

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: No formal statistical analysis was performed for this primary endpoint, as the study aimed to provide a descriptive pharmacokinetic characterization of colistin exposure in cystic fibrosis patients. The results are presented as median values with interquartile ranges, reflecting the variability in drug exposure without the need for hypothesis testing.

End point values	CMS Therapy			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: mg.h/L				
arithmetic mean (full range (min-max))	10.4 (8.4 to 12.4)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

February 2014 - May 2020

Assessment type	Systematic
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Dictionary used

Dictionary name	Inv assesment
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Dictionary version	NA
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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 non-serious adverse events were reported during the study. Patients tolerated the treatment well, and no clinically relevant adverse reactions were observed in the monitored population. This aligns with the safety profile of colistin in this specific patient group and study conditions

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