Clinical trial results:
Open-label, Multicentre Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Ceftaroline in Neonates and Young Infants with Late-Onset Sepsis

Summary

Results information

Trial information

Trial identification

Additional study identifiers

Sponsors

Paediatric regulatory details

Results analysis stage

General information about the trial

Population of trial subjects

Subjects enrolled per country

Subjects enrolled per age group

Subject disposition

Recruitment

Pre-assignment

Period 1

Arms

Arm title	

Arm title	

Arm title	

Number of subjects in period 1			

Baseline characteristics

Reporting groups	

Reporting group values			

Reporting group values			

End points

End points reporting groups	

Primary: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Discontinuations Due to Adverse Events (AEs)	

End point values				

Statistical analyses

Secondary: Plasma Concentration of Ceftaroline Fosamil

End point values				

Statistical analyses

Secondary: Plasma Concentration of Ceftaroline

End point values				

Statistical analyses

Secondary: Plasma Concentration of Ceftaroline M-1

End point values				

Statistical analyses

Secondary: Percentage of Subjects With Favorable Clinical Response

End point values				

Statistical analyses

Secondary: Percentage of Subjects With Favorable Microbiological Response

End point values				

Statistical analyses

Adverse events

Adverse events information

Dictionary used	
Reporting groups	

Serious adverse events			

Non-serious adverse events			

More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Date	Interruption	Restart date

Limitations and caveats