

Clinical trial results: ASpirin as a Treatment for ARDS (STAR) trial: a randomised, doubleblind, allocation concealed, placebo-controlled phase 2 trial. Summary

Results	information
11004100	

Trial information

Trial identification

Additional study identifiers	

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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	

Recruitment

Pre-assignment

Pre-assignment period milestones	

Period 1	

Arms	
Arm title	

Arm title	

Number of subjects in period 1	

Baseline characteristics

Reporting groups

Reporting group values		

1	1	

End points

End points reporting groups		

Primary: Oxygenation Index - Day 7		

End point values		

Statistical analyses

Statistical analysis title	
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Primary: Oxygenation index - Day 7 (Imputed)

End point values		

Statistical analysis title	

Secondary: Oxygenation Index - Day 4		

End point values		

Statistical analysis title	

Secondary: Oxygenation index - Day 14	

End point values		

Statistical analysis title	

Secondary: Respiratory Compliance - Day 4		

End point values		

Statistical analysis title	

Secondary: Respiratory Compliance - Day 7		

End point values		

Statistical analysis title	

Secondary: Respiratory Compliance - Day 14		

End point values		

Secondary: Delta SOFA - Day 4	ł		

End point values		

Statistical analysis title	

Secondary: Delta SOFA - Day 7	

End point values		

Statistical analysis title	

Secondary: Delta SOFA - Day 14	

End point values		

Secondary: PF ratio - Day 4		

End point values		

Statistical analysis title	

Secondary: PF ratio - Day 7	

End point values		

Statistical analysis title	

Secondary: PF ratio - Day 14		

End point values		

Secondary: SUSAR	

End point values		

Secondary: SOFA - Day 4			

End point values	
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End point values		

Statistical analysis title	

Secondary: SOFA - day14		

End point values		

Statistical analysis title	
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Other pre-specified: Ventilator Free Day Score		

End point values		

Statistical analysis title	

Other pre-specified: Duration of ventilation - All patients

End point values		

Statistical analysis title	

Other pre-specified: Duration of ventilation - Achieved unassisted breathing

End point values		

Other pre-specified: Duration of ventilation - Died	
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End point values		

Statistical analysis title	

Other pre-specified: Duration of ICU stay - All patients		

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Statistical analysis title	

Other pre-specified: Duration of ICU stay - Alive at discharge

End point values		

Other pre-specified: Duration of ICU stay - Died		

End point values		

Statistical analysis title	

End point values		

Statistical analysis title	

Other pre-specified: Duration of hospital stay - Alive at discharge

End point values		

Other pre-specified: Duration of hospital stay - Died		

End point values		

Statistical analysis title	

Other pre-specified: All cause mortality - 28 day			

End point values		

Statistical analysis title	

Other pre-specified: All cause mortality - 90 day		

End point values		

Statistical analysis title	

Adverse events information

Serious adverse events		

Non-serious adverse events		

More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Limitations and caveats