



Clinical trial results:

Shortened Antibiotic Treatment in Community-Acquired Pneumonia: A Nationwide Danish Randomized Controlled Trial

Summary

EudraCT number	2019-000404-15
Trial protocol	DK
Global end of trial date	22 January 2025

Results information

Result version number	v1 (current)
This version publication date	23 April 2026
First version publication date	23 April 2026

Trial information

Trial identification

Sponsor protocol code	34666
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04089787
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Thomas Benfield
Sponsor organisation address	Kettegaard Alle 30, Hvidovre, Denmark, 2650
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Scientific contact	Simone Bastrup Israelsen, Thomas Benfield, simone.elisabeth.bastrup.israelsen.02@regionh.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	08 April 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 January 2025
Global end of trial reached?	Yes
Global end of trial date	22 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy and safety of shortened antibiotic treatment duration of community-acquired pneumonia in hospitalized immunocompetent adult patients based on clinical stability criteria in a beta-lactam antibiotic setting

Protection of trial subjects:

The planned investigations and measurements are not expected to exceed usual clinical care. Pain and discomfort in relation to blood samples for adult patients are regarded insignificant. X-ray radiation in relation to initial chest X-ray is considered an acceptable radiation risk, as the approximate dose of a chest X-ray is only 0,05 mSv corresponding to 6 days of natural background radiation in Denmark.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 September 2019
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	Denmark: 395
Worldwide total number of subjects	395
EEA total number of subjects	395

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)	106
From 65 to 84 years	214
85 years and over	75

Subject disposition

Recruitment

Recruitment details:

Investigators and treating physicians associated to the research project will identify patients eligible for trial inclusion at day 1-4 after hospital admission. Eligible patients will receive verbal and written information on the study, and subsequently be offered participation.

Pre-assignment

Screening details:

Day 1 is defined by the initiation of antimicrobial therapy for CAP during hospitalization. Day 1-4 serves as screening period to determine study eligibility. Eligible patients will be included in the trial from day 1 to day 5 and randomized at day 3, 4 or 5.

Period 1

Period 1 title	Intervention (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Data analyst ^[1]

Blinding implementation details:

The trial had an open-label design, in which participants, treating physicians, and investigators were aware of treatment allocation, while outcome assessors remained blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

Patients were randomly assigned to receive either a short-course (5 days) of antibiotic treatment (intervention group) or a standard-course (≥ 7 days) of antibiotic treatment (control group). In the intervention group, antibiotic treatment was discontinued after 5 days. Antibiotic type, route, and dosage were left to physician discretion.

Arm type	Experimental
Investigational medicinal product name	piperacillin/tazobactam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for dispersion for injection
Routes of administration	Intravenous use

Dosage and administration details:

In the intervention group, antibiotic treatment was discontinued after 5 days, whereas in the control group, the duration was determined by the treating physician but had to be at least 7 days. Antibiotic type, route, and dosage were left to physician discretion.

Arm title	Control
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Arm description:

Patients were randomly assigned to receive either a short-course (5 days) of antibiotic treatment (intervention group) or a standard-course (≥ 7 days) of antibiotic treatment (control group). In the control group, the duration was determined by the treating physician but had to be at least 7 days. Antibiotic type, route, and dosage were left to physician discretion.

Arm type	Control
No investigational medicinal product assigned in this arm	

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Open-label trial, only outcome assessors remained blinded.

Number of subjects in period 1	Intervention	Control
Started	198	197
Completed	196	197
Not completed	2	0
Consent withdrawn by subject	2	-

Baseline characteristics

Reporting groups

Reporting group title	Intervention
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Reporting group description:

Patients were randomly assigned to receive either a short-course (5 days) of antibiotic treatment (intervention group) or a standard-course (≥ 7 days) of antibiotic treatment (control group). In the intervention group, antibiotic treatment was discontinued after 5 days. Antibiotic type, route, and dosage were left to physician discretion.

Reporting group title	Control
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Reporting group description:

Patients were randomly assigned to receive either a short-course (5 days) of antibiotic treatment (intervention group) or a standard-course (≥ 7 days) of antibiotic treatment (control group). In the control group, the duration was determined by the treating physician but had to be at least 7 days. Antibiotic type, route, and dosage were left to physician discretion.

Reporting group values	Intervention	Control	Total
Number of subjects	198	197	395
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	75	76	
inter-quartile range (Q1-Q3)	62 to 84	64 to 82	-
Gender categorical Units: Subjects			
Female	109	102	211
Male	89	95	184

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description: Patients were randomly assigned to receive either a short-course (5 days) of antibiotic treatment (intervention group) or a standard-course (≥ 7 days) of antibiotic treatment (control group). In the intervention group, antibiotic treatment was discontinued after 5 days. Antibiotic type, route, and dosage were left to physician discretion.	
Reporting group title	Control
Reporting group description: Patients were randomly assigned to receive either a short-course (5 days) of antibiotic treatment (intervention group) or a standard-course (≥ 7 days) of antibiotic treatment (control group). In the control group, the duration was determined by the treating physician but had to be at least 7 days. Antibiotic type, route, and dosage were left to physician discretion.	

Primary: All-cause mortality

End point title	All-cause mortality
End point description:	
End point type	Primary
End point timeframe: 90-day	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	197		
Units: deaths	6	4		

Statistical analyses

Statistical analysis title	Non-inferiority
Comparison groups	Intervention v Control
Number of subjects included in analysis	393
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	absolute risk difference
Point estimate	0
Confidence interval	
level	95 %
sides	1-sided
lower limit	-6

Secondary: Readmission

End point title	Readmission
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End point description:

End point type	Secondary
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End point timeframe:

90-day

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	197		
Units: yes/no	46	42		

Statistical analyses

No statistical analyses for this end point

Secondary: Length of hospital stay

End point title	Length of hospital stay
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End point description:

End point type	Secondary
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End point timeframe:

90 days

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	197		
Units: days				
number (not applicable)	4.0	3.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of antibiotic therapy

End point title	Duration of antibiotic therapy
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End point description:

End point type	Secondary
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End point timeframe:

90 days

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	197		
Units: days				
number (not applicable)	5.0	7.1		

Statistical analyses

No statistical analyses for this end point

Secondary: New antibiotic treatment

End point title	New antibiotic treatment
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End point description:

End point type	Secondary
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End point timeframe:

90 days

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	197		
Units: yes/no	45	38		

Statistical analyses

No statistical analyses for this end point

Secondary: Follow-up visits

End point title	Follow-up visits
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End point description:

End point type	Secondary
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End point timeframe:

90 days

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	197		
Units: yes/no	54	36		

Statistical analyses

No statistical analyses for this end point

Secondary: Mortality

End point title	Mortality
End point description:	
End point type	Secondary
End point timeframe:	
30 days	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	197		
Units: yes/no	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Readmission

End point title	Readmission
End point description:	
End point type	Secondary
End point timeframe:	
30 days	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	197		
Units: yes/no	25	18		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

90 days

Assessment type	Systematic
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Dictionary used

Dictionary name	None
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Dictionary version	0
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Reporting groups

Reporting group title	Intervention
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Reporting group description: -

Reporting group title	Control
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Reporting group description: -

Serious adverse events	Intervention	Control	
Total subjects affected by serious adverse events			
subjects affected / exposed	49 / 196 (25.00%)	49 / 197 (24.87%)	
number of deaths (all causes)	6	4	
number of deaths resulting from adverse events			
General disorders and administration site conditions			
Hospital admission/prolonged hospital stay			
subjects affected / exposed	49 / 196 (25.00%)	49 / 197 (24.87%)	
occurrences causally related to treatment / all	5 / 57	0 / 72	
deaths causally related to treatment / all	0 / 6	0 / 4	

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

Non-serious adverse events	Intervention	Control	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 196 (14.80%)	32 / 197 (16.24%)	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 196 (0.00%)	2 / 197 (1.02%)	
occurrences (all)	0	2	
Dizziness			

subjects affected / exposed occurrences (all)	1 / 196 (0.51%) 1	3 / 197 (1.52%) 3	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 196 (1.02%)	4 / 197 (2.03%)	
occurrences (all)	2	4	
Vomiting			
subjects affected / exposed	1 / 196 (0.51%)	0 / 197 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	20 / 196 (10.20%)	23 / 197 (11.68%)	
occurrences (all)	20	23	
Abdominal pain			
subjects affected / exposed	3 / 196 (1.53%)	2 / 197 (1.02%)	
occurrences (all)	3	2	
Hepatobiliary disorders			
Elevated liver enzymes			
subjects affected / exposed	2 / 196 (1.02%)	1 / 197 (0.51%)	
occurrences (all)	2	1	
Skin and subcutaneous tissue disorders			
Skin rash			
subjects affected / exposed	2 / 196 (1.02%)	1 / 197 (0.51%)	
occurrences (all)	2	1	
Renal and urinary disorders			
Elevated creatinine levels			
subjects affected / exposed	1 / 196 (0.51%)	0 / 197 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 November 2023	Change in primary outcome from composite of 90-day mortality and readmissions to only 90-day mortality and recalculation of sample size due to change in primary outcome and adjustment of confidence intervals (90% to 95%) in accordance with latest updated guidelines.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported