



## Clinical trial results:

**A single blinded multicenter randomized study comparing intubating conditions during rapid sequence induction with either suxamethonium 1.0 mg/kg or rocuronium 1.0 mg/kg in elderly patients ( 80 years old)**

### Summary

EudraCT number	2020-005384-31
Trial protocol	DK
Global end of trial date	08 March 2024

### Results information

Result version number	v1 (current)
This version publication date	29 June 2025
First version publication date	29 June 2025

### Trial information

#### Trial identification

Sponsor protocol code	RSIV80
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#### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Rigshospitalet University of Copenhagen
Sponsor organisation address	Inge Lehmanns Vej 7, Copenhagen, Denmark, 2100
Public contact	Department of Anesthesia, Rigshospitalet, 45 35457547, matias.vested@regionh.dk
Scientific contact	Department of Anesthesia, Rigshospitalet, 45 35457547, matias.vested@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	07 March 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 February 2024
Global end of trial reached?	Yes
Global end of trial date	08 March 2024
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The aim of this study is to determine the proportion of excellent tracheal intubation conditions at 60 seconds after administration of either rocuronium 1.0 mg/kg or suxamethonium 1 mg/kg in patients with age  $\geq$  80 years.

Protection of trial subjects:

Patients were anaesthetised and received standardised pain treatment according to local guidelines

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 90
Worldwide total number of subjects	90
EEA total number of subjects	90

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)	0
From 65 to 84 years	90
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

We included patients 80 years or above with American Society of Anesthesiologists (ASA) physical health class I to IV, scheduled for surgery under general anesthesia with indication for RSI intubation, and a body mass index (BMI) < 35 kg/m<sup>2</sup>.

### Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Rocuronium
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Arm description: -

Arm type	Active comparator
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Investigational medicinal product name	rocuronium
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Injection
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Routes of administration	Intravenous bolus use
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Dosage and administration details:

1 mg/kg

<b>Arm title</b>	Suxamethonium
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Arm description: -

Arm type	Experimental
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Investigational medicinal product name	suxamethonium
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Injection
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Routes of administration	Intravenous use
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Dosage and administration details:

suxamethonium 1 mg/kg

<b>Number of subjects in period 1</b>	Rocuronium	Suxamethonium
Started	49	41
Completed	49	41



## Baseline characteristics

### Reporting groups

Reporting group title	Rocuronium
Reporting group description: -	
Reporting group title	Suxamethonium
Reporting group description: -	

Reporting group values	Rocuronium	Suxamethonium	Total
Number of subjects	49	41	90
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			
arithmetic mean	83	84	
standard deviation	± 3	± 3	-
Gender categorical Units: Subjects			
Female	28	22	50
Male	21	19	40

## End points

### End points reporting groups

Reporting group title	Rocuronium
Reporting group description:	-
Reporting group title	Suxamethonium
Reporting group description:	-

### Primary: optimal intubating conditions

End point title	optimal intubating conditions
End point description:	
End point type	Primary
End point timeframe:	From start of anaesthesia till tracheal intubation within 15 minutes

End point values	Rocuronium	Suxamethonium		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	41		
Units: number	36	31		

### Statistical analyses

Statistical analysis title	Qi square test for proportions
Comparison groups	Rocuronium v Suxamethonium
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Chi-squared
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided

### Secondary: time to tracheal intubation

End point title	time to tracheal intubation
End point description:	
End point type	Secondary

End point timeframe:  
from start of anaesthesia till tracheal intubation

<b>End point values</b>	Rocuronium	Suxamethonium		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	41		
Units: minute				
arithmetic mean (standard deviation)	159 ( $\pm$ 33)	154 ( $\pm$ 31)		

### Statistical analyses

<b>Statistical analysis title</b>	t test
Comparison groups	Rocuronium v Suxamethonium
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	2-sided

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

from start of anaesthesia till 3 days postoperatively

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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### Reporting groups

Reporting group title	Rocuronium
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Reporting group description: -

Reporting group title	Suxamethonium
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Reporting group description: -

<b>Serious adverse events</b>	Rocuronium	Suxamethonium	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 49 (14.29%)	1 / 41 (2.44%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
bleeding			
subjects affected / exposed	2 / 49 (4.08%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
impaired vision			
subjects affected / exposed	1 / 49 (2.04%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	1 / 49 (2.04%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory, thoracic and mediastinal disorders</b>			
Desaturation			
subjects affected / exposed	1 / 49 (2.04%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
muscle weakness			
subjects affected / exposed	0 / 49 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
fever			
subjects affected / exposed	1 / 49 (2.04%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

<b>Non-serious adverse events</b>	Rocuronium	Suxamethonium	
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	11 / 49 (22.45%)	17 / 41 (41.46%)	
<b>Cardiac disorders</b>			
ECG changes			
subjects affected / exposed	1 / 49 (2.04%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
<b>Blood and lymphatic system disorders</b>			
Edema			
subjects affected / exposed	1 / 49 (2.04%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
<b>Eye disorders</b>			
Double vision			

subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	1 / 41 (2.44%) 1	
Respiratory, thoracic and mediastinal disorders bronchospasm subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	2 / 41 (4.88%) 2	
Musculoskeletal and connective tissue disorders Postoperative muscle weakness subjects affected / exposed occurrences (all)	7 / 49 (14.29%) 7	12 / 41 (29.27%) 12	

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported

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### **Online references**

<http://www.ncbi.nlm.nih.gov/pubmed/39910022>