



## 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 |
|-----------------------|--------|

#### 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:

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**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:

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**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:

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**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:

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**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 |
|------------------------------|-----|

|                  |            |
|------------------|------------|
| <b>Arm title</b> | Rocuronium |
|------------------|------------|

Arm description: -

|                                        |                       |
|----------------------------------------|-----------------------|
| Arm type                               | Active comparator     |
| Investigational medicinal product name | rocuronium            |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Injection             |
| Routes of administration               | Intravenous bolus use |

Dosage and administration details:

1 mg/kg

|                  |               |
|------------------|---------------|
| <b>Arm title</b> | Suxamethonium |
|------------------|---------------|

Arm description: -

|                                        |                 |
|----------------------------------------|-----------------|
| Arm type                               | Experimental    |
| Investigational medicinal product name | suxamethonium   |
| Investigational medicinal product code |                 |
| Other name                             |                 |
| Pharmaceutical forms                   | Injection       |
| Routes of administration               | Intravenous use |

Dosage and administration details:

suxamethonium 1 mg/kg

| Number of subjects in period 1 | 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<br>Units: Subjects                    |            |               |       |
| In utero                                              |            |               | 0     |
| Preterm newborn infants<br>(gestational age < 37 wks) |            |               | 0     |
| Newborns (0-27 days)                                  |            |               | 0     |
| Infants and toddlers (28 days-23<br>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<br>Units: years                        |            |               |       |
| arithmetic mean                                       | 83         | 84            |       |
| standard deviation                                    | ± 3        | ± 3           | -     |
| Gender categorical<br>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

| End point values                     | 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

| Statistical analysis title              | 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 |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |   |
|--------------------|---|
| Dictionary version | 1 |
|--------------------|---|

### Reporting groups

|                       |            |
|-----------------------|------------|
| Reporting group title | Rocuronium |
|-----------------------|------------|

Reporting group description: -

|                       |               |
|-----------------------|---------------|
| Reporting group title | Suxamethonium |
|-----------------------|---------------|

Reporting group description: -

| Serious adverse events                            | 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          |  |
| Respiratory, thoracic and mediastinal disorders |                |                |  |
| 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          |  |
| Musculoskeletal and connective tissue disorders |                |                |  |
| 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          |  |
| Infections and infestations                     |                |                |  |
| 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    |  |
|-------------------------------------------------------|------------------|------------------|--|
| Total subjects affected by non-serious adverse events |                  |                  |  |
| subjects affected / exposed                           | 11 / 49 (22.45%) | 17 / 41 (41.46%) |  |
| Cardiac disorders                                     |                  |                  |  |
| ECG changes                                           |                  |                  |  |
| subjects affected / exposed                           | 1 / 49 (2.04%)   | 0 / 41 (0.00%)   |  |
| occurrences (all)                                     | 1                | 0                |  |
| Blood and lymphatic system disorders                  |                  |                  |  |
| Edema                                                 |                  |                  |  |
| subjects affected / exposed                           | 1 / 49 (2.04%)   | 2 / 41 (4.88%)   |  |
| occurrences (all)                                     | 1                | 2                |  |
| Eye disorders                                         |                  |                  |  |
| Double vision                                         |                  |                  |  |

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