



## Clinical trial results: Treatment of MRSA throat carriage with mupirocin irrigation Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2014-005308-12   |
| Trial protocol           | DK               |
| Global end of trial date | 01 December 2020 |

### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 19 December 2021 |
| First version publication date | 19 December 2021 |

### Trial information

#### Trial identification

|                       |      |
|-----------------------|------|
| Sponsor protocol code | 1111 |
|-----------------------|------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |                                                                                                                                   |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Region Sjælland, Slagelse Hospital                                                                                                |
| Sponsor organisation address | Ingemannsvej 18, Slagelse, Denmark, 4200                                                                                          |
| Public contact               | Head of Research and Innovation, Region Sjælland,<br>Operations, Research and Innovation, 45 58559404,<br>insp@regionsjaelland.dk |
| Scientific contact           | Head of Research and Innovation, Region Sjælland,<br>Operations, Research and Innovation, 45 58559404,<br>insp@regionsjaelland.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                       | 01 June 2021      |
| Is this the analysis of the primary completion data? | Yes               |
| Primary completion date                              | 17 September 2020 |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 01 December 2020  |
| Was the trial ended prematurely?                     | No                |

Notes:

## General information about the trial

Main objective of the trial:

To determine if irrigation and wash of, respectively, the rhinopharynx and mouth with dissolved mupirocin is a feasible and potentially efficacious supplementary strategy against treatment resistant MRSA throat carriage.

Protection of trial subjects:

The patient was given all treatment instruction, including irrigation technique by a personal visit of the sponsor. Furthermore, the infection control nurse contacted the patient by phone in the beginning, in the middle and in the end of the treatment period, to ask how the treatment was going and to answer any questions the patient might have.

Background therapy: -

Evidence for comparator: -

|                                                           |             |
|-----------------------------------------------------------|-------------|
| Actual start date of recruitment                          | 01 May 2018 |
| 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: 20 |
| Worldwide total number of subjects   | 20          |
| EEA total number of subjects         | 20          |

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)                      | 14 |
| From 65 to 84 years                       | 6  |

|                   |   |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

## Subject disposition

### Recruitment

Recruitment details:

The study was performed at the outpatient MRSA sections of three Departments of Clinical Microbiology (Slagelse Hospital, Herlev Hospital, and Hvidovre Hospital) covering all outpatients in two neighboring regions of East-Denmark; Region Zealand and The Capital Region. Approximately 2,7 million citizens live in these two regions.

### Pre-assignment

Screening details:

The design and study group was an open, non-blinded, trial of a cohort of 20 patients. None of the patients were hospitalized and all were living in their own home. All patients received the same treatment.

Inclusion of patients was done by medical assessment in the two regions in the participating MRSA units and microbiological departments.

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall trial (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Not applicable                 |
| Blinding used                | Not blinded                    |

Blinding implementation details:

No blinding

### Arms

| Arm title                              | End-point data                                                                                                       |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| Arm description: -                     |                                                                                                                      |
| Arm type                               | All subjects                                                                                                         |
| Investigational medicinal product name | mupirocin ointment (22 g 2% ointment per liter of isotonic sterile saline solution) in a 37 degrees Celsius solution |
| Investigational medicinal product code |                                                                                                                      |
| Other name                             |                                                                                                                      |
| Pharmaceutical forms                   | Nasal/oromucosal spray, solution, Gargle/mouthwash                                                                   |
| Routes of administration               | Other use                                                                                                            |

Dosage and administration details:

For each patient, mupirocin ointment 2% (GlaxoSmithKline) was dispensed into 28 small bottles for treatments twice a day in 14 days, each bottle with an amount of ointment equivalent to a treatment. The ointment from a bottle was by the patient mixed with 37°C 120 ml of a sterile fluid of saline 0.9% prior to each treatment to achieve the right amount of mupirocin solution (22 g 2% ointment per liter of isotonic sterile saline solution) [9]. The temperature of the solution was controlled by a thermometer that each patient received prior to the treatment.

The patient performed rhinopharynx irrigation and mouth gurgling with a mupirocin solution every morning and evening for 14 days. Rhinopharynx irrigation was performed using a Neti pot (Rhinohorn, Yogaprosess AS, Norway) through each nostril with 50 mL mupirocin solution twice daily, and also mouth gurgle with 20 mL mupirocin solution in 20 seconds was done twice daily.

| <b>Number of subjects in period 1</b> | End-point data |
|---------------------------------------|----------------|
| Started                               | 20             |
| Completed                             | 18             |
| Not completed                         | 2              |
| Protocol deviation                    | 2              |

## Baseline characteristics

### Reporting groups

Reporting group title

Overall trial

Reporting group description: -

| Reporting group values                                | Overall trial | Total |  |
|-------------------------------------------------------|---------------|-------|--|
| Number of subjects                                    | 20            | 20    |  |
| Age categorical                                       |               |       |  |
| Units: Subjects                                       |               |       |  |
| In utero                                              | 0             | 0     |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0             | 0     |  |
| Newborns (0-27 days)                                  | 0             | 0     |  |
| Infants and toddlers (28 days-23<br>months)           | 0             | 0     |  |
| Children (2-11 years)                                 | 0             | 0     |  |
| Adolescents (12-17 years)                             | 0             | 0     |  |
| Adults (18-64 years)                                  | 14            | 14    |  |
| From 65-84 years                                      | 6             | 6     |  |
| 85 years and over                                     | 0             | 0     |  |
| Gender categorical                                    |               |       |  |
| Units: Subjects                                       |               |       |  |
| Female                                                | 12            | 12    |  |
| Male                                                  | 8             | 8     |  |

## End points

### End points reporting groups

|                                |                |
|--------------------------------|----------------|
| Reporting group title          | End-point data |
| Reporting group description: - |                |

### Primary: Number of trial subjects with negativ MRSA podning at 6 months

|                 |                                                                               |
|-----------------|-------------------------------------------------------------------------------|
| End point title | Number of trial subjects with negativ MRSA podning at 6 months <sup>[1]</sup> |
|-----------------|-------------------------------------------------------------------------------|

End point description:

Before start of treatment, as well as six months after end of treatment, swabs were collected from nose, throat and perineum (the latter only one time before start of treatment) by the patients general practitioner as recommended in "Guidance on preventing the spread of MRSA" by the Danish Health Authority [2]. All samples were collected using ESwab (COPAN Diagnostics, Murrieta, California).

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

6 months after intervention

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Please see the attachment. Result

| End point values            | End-point data  |  |  |  |
|-----------------------------|-----------------|--|--|--|
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 15              |  |  |  |
| Units: Number               | 7               |  |  |  |

### Attachments (see zip file)

Result/Table 1.pdf

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of trial subjects with negativ MRSA podning at 1 month

|                 |                                                               |
|-----------------|---------------------------------------------------------------|
| End point title | Number of trial subjects with negativ MRSA podning at 1 month |
|-----------------|---------------------------------------------------------------|

End point description:

Before start of treatment and after one month after end of treatment, swabs were collected from nose, throat and perineum (the latter only one time before start of treatment) by the patients general practitioner as recommended in "Guidance on preventing the spread of MRSA" by the Danish Health Authority [2]. All samples were collected using ESwab (COPAN Diagnostics, Murrieta, California).

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Number of subjects with a negative MRSA podning one month after intervention

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | End-point data  |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 18              |  |  |  |
| Units: Number               | 15              |  |  |  |

### Statistical analyses

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No statistical analyses for this end point



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From informed consent to end of intervention

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

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

|                    |   |
|--------------------|---|
| Dictionary version | 0 |
|--------------------|---|

### Reporting groups

|                       |           |
|-----------------------|-----------|
| Reporting group title | All trail |
|-----------------------|-----------|

Reporting group description: -

| <b>Serious adverse events</b>                     | All trail      |  |  |
|---------------------------------------------------|----------------|--|--|
| Total subjects affected by serious adverse events |                |  |  |
| subjects affected / exposed                       | 0 / 18 (0.00%) |  |  |
| number of deaths (all causes)                     | 0              |  |  |
| number of deaths resulting from adverse events    | 0              |  |  |

Frequency threshold for reporting non-serious adverse events: 1 %

| <b>Non-serious adverse events</b>                     | All trail       |  |  |
|-------------------------------------------------------|-----------------|--|--|
| Total subjects affected by non-serious adverse events |                 |  |  |
| subjects affected / exposed                           | 7 / 18 (38.89%) |  |  |
| Nervous system disorders                              |                 |  |  |
| headache                                              |                 |  |  |
| subjects affected / exposed                           | 3 / 18 (16.67%) |  |  |
| occurrences (all)                                     | 2               |  |  |
| Respiratory, thoracic and mediastinal disorders       |                 |  |  |
| Fluid running from the nose                           |                 |  |  |
| subjects affected / exposed                           | 3 / 18 (16.67%) |  |  |
| occurrences (all)                                     | 2               |  |  |
| Few episodes with sneezing                            |                 |  |  |
| subjects affected / exposed                           | 2 / 18 (11.11%) |  |  |
| occurrences (all)                                     | 2               |  |  |
| Metabolism and nutrition disorders                    |                 |  |  |

|                                                                            |                      |  |  |
|----------------------------------------------------------------------------|----------------------|--|--|
| Bad taste in the mouth<br>subjects affected / exposed<br>occurrences (all) | 2 / 18 (11.11%)<br>2 |  |  |
|----------------------------------------------------------------------------|----------------------|--|--|

## 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/34699965>