



## Clinical trial results:

### Open label Randomized Controlled clinical Trial of vedolizumab versus conventional treatment for Checkpoint Inhibitor induced Colitis

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2020-005793-10   |
| Trial protocol           | DK               |
| Global end of trial date | 30 November 2024 |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 28 March 2026 |
| First version publication date | 28 March 2026 |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | 01012121 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04797325 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Copenhagen university hospital Herlev  |
| Sponsor organisation address | Borgmester Ib Juuls vej 1, Herlev, Denmark, 2730   |
| Public contact               | Emilie Kristine Dahl, Jakob Benedict Seidelin, 45 35452514, jakob.benedict.seidelin@regionh.dk |
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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                              | 30 November 2024 |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 30 November 2024 |
| Was the trial ended prematurely?                     | Yes              |

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this trial is to evaluate the safety and efficacy of vedolizumab as a first line treatment of immune check point inhibitor (ICPI) induced colitis.

Protection of trial subjects:

We performed a planned safety analysis after 10 patients had received the trial drug vedolizumab to ensure clinical response.

Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 11 November 2021 |
| 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: 41 |
| Worldwide total number of subjects   | 41          |
| EEA total number of subjects         | 41          |

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)                      | 23 |
| From 65 to 84 years                       | 18 |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Patients were recruited from the out patient clinic and from the ward

### Period 1

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

Blinding implementation details:

Patients were randomly assigned in a 1:1 ratio using a computer-generated sequence. A research assistant, without involvement in the trial, generated sealed opaque envelopes with the randomization code.

### Arms

|                              |             |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes         |
| <b>Arm title</b>             | Vedolizumab |

Arm description: -

|  |   |
|--|---|
| Arm type                               | Experimental  |
| Investigational medicinal product name | vedolizumab   |
| Investigational medicinal product code |   |
| Other name                             |   |
| Pharmaceutical forms                   | Concentrate and solvent for concentrate for solution for infusion |
| Routes of administration               | Infusion  |

Dosage and administration details:

Patients receiving vedolizumab 300 mg IV at week 0, 2, 6, 14, 22.

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

Arm description:

Standard treatment with corticosteroids and infliximab rescue treatment at treatment failure to corticosteroids

|  |   |
|--|---|
| Arm type                               | Active comparator                                       |
| Investigational medicinal product name | corticosteroid  |
| Investigational medicinal product code |   |
| Other name                             | Prednisolone  |
| Pharmaceutical forms                   | Tablet, Powder and solvent for dispersion for injection |
| Routes of administration               | Injection , Oral use                                    |

Dosage and administration details:

Corticosteroids were administered and tapered accordingly to symptoms.

| <b>Number of subjects in period 1</b> | Vedolizumab | Conventionel |
|---------------------------------------|-------------|--------------|
| Started                               | 22          | 19           |
| Completed                             | 20          | 18           |
| Not completed                         | 2           | 1            |
| Lost to follow-up                     | 2           | 1            |

## Baseline characteristics

### Reporting groups

|   |              |
|---|--------------|
| Reporting group title   | Vedolizumab  |
| Reporting group description: -  |              |
| Reporting group title   | Conventionel |
| Reporting group description:  |              |
| Standard treatment with corticosteroids and infliximab rescue treatment at treatment failure to corticosteroids |              |

| Reporting group values                             | Vedolizumab | Conventionel | Total |
|--|-------------|--------------|-------|
| Number of subjects                                 | 22          | 19           | 41    |
| Age categorical                                    |             |              |       |
| Units: Subjects                                    |             |              |       |
| In utero   | 0           | 0            | 0     |
| Preterm newborn infants (gestational age < 37 wks) | 0           | 0            | 0     |
| Newborns (0-27 days)                               | 0           | 0            | 0     |
| Infants and toddlers (28 days-23 months)           | 0           | 0            | 0     |
| Children (2-11 years)                              | 0           | 0            | 0     |
| Adolescents (12-17 years)                          | 0           | 0            | 0     |
| Adults (18-64 years)                               | 13          | 11           | 24    |
| From 65-84 years                                   | 9           | 8            | 17    |
| 85 years and over                                  | 0           | 0            | 0     |
| adults   | 0           | 0            | 0     |
| Gender categorical                                 |             |              |       |
| Units: Subjects                                    |             |              |       |
| Female   | 7           | 5            | 12    |
| Male   | 15          | 14           | 29    |

## End points

### End points reporting groups

|                              |   |
|------------------------------|---|
| Reporting group title        | Vedolizumab   |
| Reporting group description: | -   |
| Reporting group title        | Conventional  |
| Reporting group description: | Standard treatment with corticosteroids and infliximab rescue treatment at treatment failure to corticosteroids |

### Primary: cumulative dose of corticosteroids at week 30

|                        |   |
|------------------------|---|
| End point title        | cumulative dose of corticosteroids at week 30 |
| End point description: | cumulative dose of corticosteroids at week 30 |
| End point type         | Primary                                       |
| End point timeframe:   | From randomisation to week 30                 |

| End point values                     | Vedolizumab       | Conventional      |  |  |
|--------------------------------------|-------------------|-------------------|--|--|
| Subject group type                   | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed          | 21                | 18                |  |  |
| Units: mg                            |                   |                   |  |  |
| arithmetic mean (standard deviation) | 1378 ( $\pm$ 447) | 2390 ( $\pm$ 384) |  |  |

### Statistical analyses

|   |                            |
|---|----------------------------|
| Statistical analysis title              | primary outcome            |
| Comparison groups                       | Vedolizumab v Conventional |
| Number of subjects included in analysis | 39                         |
| Analysis specification                  | Pre-specified              |
| Analysis type                           | equivalence <sup>[1]</sup> |
| P-value                                 | = 0.107 <sup>[2]</sup>     |
| Method                                  | welch's t-test             |

Notes:

[1] - We will use the 30-weeks survivors analysis set. Missing data for the patient(s) lost to follow-up will be imputed and transparently reported. Because of the small sample size, the main analysis will consist of a simple unadjusted analysis a Welch's t-test analysis. The empirical (i.e. observed) means in each group and their difference will be reported, together with the corresponding 95% two-sided confidence intervals.

[2] - A two sided p-value for the null of hypothesis of no difference in mean will be reported. That is, the standard output of the call to the t.test() function of R will be reported.

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Each patient had adverse events registered from entering the trial at randomisation and until the trial period ended 30 weeks later.

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

### Dictionary used

|                    |       |
|--------------------|-------|
| Dictionary name    | CTCAE |
| Dictionary version | 5     |

### Reporting groups

|                       |             |
|-----------------------|-------------|
| Reporting group title | vedolizumab |
|-----------------------|-------------|

Reporting group description:

patients in the vedolizumab arm

|                       |              |
|-----------------------|--------------|
| Reporting group title | conventionel |
|-----------------------|--------------|

Reporting group description: -

| Serious adverse events                               | vedolizumab      | conventionel     |  |
|--|------------------|------------------|--|
| Total subjects affected by serious adverse events    |                  |                  |  |
| subjects affected / exposed                          | 13 / 22 (59.09%) | 11 / 19 (57.89%) |  |
| number of deaths (all causes)                        | 1                | 1                |  |
| number of deaths resulting from adverse events       | 0                | 0                |  |
| Surgical and medical procedures                      |                  |                  |  |
| bone fracture  |                  |                  |  |
| subjects affected / exposed                          | 0 / 22 (0.00%)   | 1 / 19 (5.26%)   |  |
| occurrences causally related to treatment / all      | 0 / 0            | 0 / 1            |  |
| deaths causally related to treatment / all           | 0 / 0            | 0 / 0            |  |
| General disorders and administration site conditions |                  |                  |  |
| planned cancer operation                             |                  |                  |  |
| subjects affected / exposed                          | 1 / 22 (4.55%)   | 2 / 19 (10.53%)  |  |
| occurrences causally related to treatment / all      | 0 / 1            | 0 / 2            |  |
| deaths causally related to treatment / all           | 0 / 0            | 0 / 0            |  |
| pain   |                  |                  |  |
| subjects affected / exposed                          | 1 / 22 (4.55%)   | 1 / 19 (5.26%)   |  |
| occurrences causally related to treatment / all      | 0 / 1            | 0 / 1            |  |
| deaths causally related to treatment / all           | 0 / 0            | 0 / 0            |  |
| electrolyte disturbance                              |                  |                  |  |

|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 19 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| vitamin insufficiency                           |                |                |  |
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 19 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Dizziness                                       |                |                |  |
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 19 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| depression                                      |                |                |  |
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 19 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| dehydration                                     |                |                |  |
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 19 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Blood and lymphatic system disorders            |                |                |  |
| Pulmonary embolism                              |                |                |  |
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 19 (0.00%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Neutropenia                                     |                |                |  |
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 19 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Immune system disorders                         |                |                |  |
| anaphylaxis                                     |                |                |  |
| subjects affected / exposed                     | 1 / 22 (4.55%) | 1 / 19 (5.26%) |  |
| occurrences causally related to treatment / all | 1 / 1          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Gastrointestinal disorders                      |                |                |  |



|   |  |                 |  |
|---|--|-----------------|--|
| Diarrhea  | Additional description: diarrhea           |                 |  |
| subjects affected / exposed                     | 7 / 22 (31.82%)                            | 7 / 19 (36.84%) |  |
| occurrences causally related to treatment / all | 0 / 7                                      | 1 / 7           |  |
| deaths causally related to treatment / all      | 0 / 0                                      | 0 / 0           |  |
| rectal bleeding                                 |  |                 |  |
| subjects affected / exposed                     | 1 / 22 (4.55%)                             | 0 / 19 (0.00%)  |  |
| occurrences causally related to treatment / all | 1 / 1                                      | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0                                      | 0 / 0           |  |
| nausea  |  |                 |  |
| subjects affected / exposed                     | 1 / 22 (4.55%)                             | 0 / 19 (0.00%)  |  |
| occurrences causally related to treatment / all | 0 / 1                                      | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0                                      | 0 / 0           |  |
| obstipation                                     |  |                 |  |
| subjects affected / exposed                     | 1 / 22 (4.55%)                             | 0 / 19 (0.00%)  |  |
| occurrences causally related to treatment / all | 0 / 1                                      | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0                                      | 0 / 0           |  |
| intestinal perforation                          | Additional description: at index endoscopy |                 |  |
| subjects affected / exposed                     | 1 / 22 (4.55%)                             | 0 / 19 (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 |  |                 |  |
| Pneumonitis                                     |  |                 |  |
| subjects affected / exposed                     | 0 / 22 (0.00%)                             | 1 / 19 (5.26%)  |  |
| occurrences causally related to treatment / all | 0 / 0                                      | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0                                      | 0 / 0           |  |
| Renal and urinary disorders                     |  |                 |  |
| nephritis                                       |  |                 |  |
| subjects affected / exposed                     | 1 / 22 (4.55%)                             | 0 / 19 (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 pain                                     |  |                 |  |

|   |                |                 |  |
|---|----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 19 (0.00%)  |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           |  |
| <b>Infections and infestations</b>              |                |                 |  |
| infections                                      |                |                 |  |
| subjects affected / exposed                     | 2 / 22 (9.09%) | 8 / 19 (42.11%) |  |
| occurrences causally related to treatment / all | 1 / 2          | 3 / 8           |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           |  |

Frequency threshold for reporting non-serious adverse events: 5 %

| <b>Non-serious adverse events</b>                            | vedolizumab       | conventionel      |  |
|--|-------------------|-------------------|--|
| <b>Total subjects affected by non-serious adverse events</b> |                   |                   |  |
| subjects affected / exposed                                  | 22 / 22 (100.00%) | 19 / 19 (100.00%) |  |
| <b>Nervous system disorders</b>                              |                   |                   |  |
| Headache   |                   |                   |  |
| subjects affected / exposed                                  | 7 / 22 (31.82%)   | 8 / 19 (42.11%)   |  |
| occurrences (all)  | 7                 | 8                 |  |
| <b>General disorders and administration site conditions</b>  |                   |                   |  |
| Dizziness  |                   |                   |  |
| subjects affected / exposed                                  | 3 / 22 (13.64%)   | 5 / 19 (26.32%)   |  |
| occurrences (all)  | 3                 | 5                 |  |
| Performance status decreased                                 |                   |                   |  |
| subjects affected / exposed                                  | 6 / 22 (27.27%)   | 7 / 19 (36.84%)   |  |
| occurrences (all)  | 6                 | 7                 |  |
| Fatigue  |                   |                   |  |
| subjects affected / exposed                                  | 6 / 22 (27.27%)   | 7 / 19 (36.84%)   |  |
| occurrences (all)  | 6                 | 7                 |  |
| hyperactive bladder  |                   |                   |  |
| subjects affected / exposed                                  | 1 / 22 (4.55%)    | 3 / 19 (15.79%)   |  |
| occurrences (all)  | 1                 | 3                 |  |
| Insomnia   |                   |                   |  |
| subjects affected / exposed                                  | 0 / 22 (0.00%)    | 3 / 19 (15.79%)   |  |
| occurrences (all)  | 0                 | 3                 |  |
| <b>Blood and lymphatic system disorders</b>                  |                   |                   |  |

|                             |                           |                 |  |
|-----------------------------|---------------------------|-----------------|--|
| Anaemia                     |                           |                 |  |
| subjects affected / exposed | 7 / 22 (31.82%)           | 4 / 19 (21.05%) |  |
| occurrences (all)           | 7                         | 4               |  |
| bruises                     |                           |                 |  |
| subjects affected / exposed | 1 / 22 (4.55%)            | 5 / 19 (26.32%) |  |
| occurrences (all)           | 1                         | 5               |  |
| Eye disorders               |                           |                 |  |
| visual sharpness decreased  |                           |                 |  |
| subjects affected / exposed | 5 / 22 (22.73%)           | 4 / 19 (21.05%) |  |
| occurrences (all)           | 5                         | 4               |  |
| dry eyes                    |                           |                 |  |
| subjects affected / exposed | 3 / 22 (13.64%)           | 1 / 19 (5.26%)  |  |
| occurrences (all)           | 3                         | 1               |  |
| Gastrointestinal disorders  |                           |                 |  |
| Nausea                      | Additional description: x |                 |  |
| subjects affected / exposed | 6 / 22 (27.27%)           | 5 / 19 (26.32%) |  |
| occurrences (all)           | 6                         | 5               |  |
| obstipation                 |                           |                 |  |
| subjects affected / exposed | 5 / 22 (22.73%)           | 5 / 19 (26.32%) |  |
| occurrences (all)           | 5                         | 5               |  |
| electrolyte disturbance     |                           |                 |  |
| subjects affected / exposed | 5 / 22 (22.73%)           | 4 / 19 (21.05%) |  |
| occurrences (all)           | 5                         | 4               |  |
| vitamin insufficiency       | Additional description: x |                 |  |
| subjects affected / exposed | 5 / 22 (22.73%)           | 2 / 19 (10.53%) |  |
| occurrences (all)           | 5                         | 2               |  |
| oral mucositis              |                           |                 |  |
| subjects affected / exposed | 6 / 22 (27.27%)           | 8 / 19 (42.11%) |  |
| occurrences (all)           | 6                         | 8               |  |
| vomiting                    |                           |                 |  |
| subjects affected / exposed | 4 / 22 (18.18%)           | 1 / 19 (5.26%)  |  |
| occurrences (all)           | 4                         | 1               |  |
| Dry mouth                   |                           |                 |  |
| subjects affected / exposed | 3 / 22 (13.64%)           | 1 / 19 (5.26%)  |  |
| occurrences (all)           | 3                         | 1               |  |
| stomach pain                |                           |                 |  |

|   |                      |                      |  |
|---|----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)  | 2 / 22 (9.09%)<br>2  | 4 / 19 (21.05%)<br>4 |  |
| Pancreatitis<br>subjects affected / exposed<br>occurrences (all)  | 1 / 22 (4.55%)<br>1  | 4 / 19 (21.05%)<br>4 |  |
| anal pain<br>subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0  | 2 / 19 (10.53%)<br>2 |  |
| Respiratory, thoracic and mediastinal disorders<br>Dyspnoea<br>subjects affected / exposed<br>occurrences (all) | 6 / 22 (27.27%)<br>6 | 7 / 19 (36.84%)<br>7 |  |
| Hepatobiliary disorders<br>Hepatitis<br>subjects affected / exposed<br>occurrences (all)                        | 5 / 22 (22.73%)<br>5 | 5 / 19 (26.32%)<br>5 |  |
| Skin and subcutaneous tissue disorders<br>Rash<br>subjects affected / exposed<br>occurrences (all)              | 2 / 22 (9.09%)<br>2  | 6 / 19 (31.58%)<br>6 |  |
| sensory disturbance<br>subjects affected / exposed<br>occurrences (all)   | 1 / 22 (4.55%)<br>1  | 2 / 19 (10.53%)<br>2 |  |
| vitiligo<br>subjects affected / exposed<br>occurrences (all)  | 1 / 22 (4.55%)<br>1  | 2 / 19 (10.53%)<br>2 |  |
| moon face<br>subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0  | 2 / 19 (10.53%)<br>2 |  |
| Endocrine disorders<br>Hypothyroidism<br>subjects affected / exposed<br>occurrences (all)                       | 2 / 22 (9.09%)<br>2  | 2 / 19 (10.53%)<br>2 |  |
| Osteoporosis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 22 (0.00%)<br>0  | 2 / 19 (10.53%)<br>2 |  |

|   |                           |                  |  |
|---|---------------------------|------------------|--|
| Musculoskeletal and connective tissue disorders |                           |                  |  |
| muscle pain                                     | Additional description: x |                  |  |
| subjects affected / exposed                     | 4 / 22 (18.18%)           | 10 / 19 (52.63%) |  |
| occurrences (all)                               | 4                         | 10               |  |
| joint pain                                      |                           |                  |  |
| subjects affected / exposed                     | 7 / 22 (31.82%)           | 4 / 19 (21.05%)  |  |
| occurrences (all)                               | 7                         | 4                |  |
| puritus   |                           |                  |  |
| subjects affected / exposed                     | 7 / 22 (31.82%)           | 1 / 19 (5.26%)   |  |
| occurrences (all)                               | 7                         | 1                |  |
| periferal odema                                 |                           |                  |  |
| subjects affected / exposed                     | 3 / 22 (13.64%)           | 5 / 19 (26.32%)  |  |
| occurrences (all)                               | 3                         | 5                |  |
| Infections and infestations                     |                           |                  |  |
| infections                                      | Additional description: x |                  |  |
| subjects affected / exposed                     | 10 / 22 (45.45%)          | 8 / 19 (42.11%)  |  |
| occurrences (all)                               | 16                        | 14               |  |
| fever without infection                         |                           |                  |  |
| subjects affected / exposed                     | 3 / 22 (13.64%)           | 1 / 19 (5.26%)   |  |
| occurrences (all)                               | 3                         | 1                |  |
| Metabolism and nutrition disorders              |                           |                  |  |
| nefritis  |                           |                  |  |
| subjects affected / exposed                     | 2 / 22 (9.09%)            | 0 / 19 (0.00%)   |  |
| occurrences (all)                               | 2                         | 0                |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment  |
|-----------------|--|
| 17 January 2022 | Change of inclusion and exclusion criteria. We broaden the inclusion criteria to also include hospitalized patients. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported