



Clinical trial results:

Efficacy and safety of novel treatment options for adults with COVID-19 pneumonia. A double-blinded, randomized, multi-stage, 6-armed placebo-controlled trial in the framework of an adaptive trial platform

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2020-001367-88 |
| Trial protocol | DK |
| Global end of trial date | 17 June 2020 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 (current) |
| This version publication date | 27 September 2020 |
| First version publication date | 27 September 2020 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | 25032020 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04345289 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Thomas Benfield |
| Sponsor organisation address | Kettegaard Alle 30, Hvidovre, Denmark, 2650 |
| Public contact | Charlotte Kastberg Levin, Department of infectious diseases, +45 38622941, charlotte.kastberg.levin.01@regionh.dk |
| Scientific contact | Charlotte Kastberg Levin, Department of infectious diseases, +45 38622941, charlotte.kastberg.levin.01@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 | 11 August 2020 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|--------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 17 June 2020 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to evaluate the efficacy and safety of convalescent anti-SARS-CoV-2 plasma, hydroxychloroquine, sarilumab and baricitinib compared with placebo in combination with standard of care (SOC) for the treatment of moderate-to-severe COVID-19 pneumonia on the basis of the composite endpoint: All-cause mortality or need of invasive mechanical ventilation up to 28 days.

Protection of trial subjects:

The adaptive study design allowed each treatment group to be evaluated separately. If necessary, each treatment group could be discontinued due to futility, effect, safety or new knowledge on specific treatment of COVID-19.

This was the case for hydroxychloroquine which was withdrawn from the study 2020-06-09 due to new research results (from other studies) indicating severe adverse events, when giving to COVID-19 patients.

Due to the introduction of dexamethason (and Remdesevir) as first line treatment, we considered it unnecessary to continue baricitinib and sarilumab as the effect immuno-suppressive.

The trial will continue as a non-drug trial with convalescence SARS-CoV-2 plasma.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 16 April 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: 6 |
| Worldwide total number of subjects | 6 |
| EEA total number of subjects | 6 |

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) | 4 |
| From 65 to 84 years | 1 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details:

Recruitment period went from 01-05-2020 to 11-06-2020.

Only one sites was initiated, and all 6 patients were recruited from and hospitalized at Hvidovre Hospital, Denmark.

All patients with SARS-Covid-19 positive swap or traceal sputum hospitalized patiens during the period were screened for participation by treating physicians.

Pre-assignment

Screening details:

60 patients in total went through screening.

Period 1

| | |
|------------------------------|---|
| Period 1 title | Inclusion (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

Blinding implementation details:

Eligible patients who signed informed content, were enrolled. Randomization was performed in RedCap by unblinded personel. Patients were randomized to one of the six study arms. Study treatment were prepared and administrated by unblinded personel. All six patients were randomized to oral treatment. All oral treatment were capsulated in identical opaque capsules to maintain blinding for all other personel than the unblinded personel.

Arms

| | |
|------------------------------|-------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Hydroxychloroquin |

Arm description:

Hydroxychloroquine (Plaquenil) (capsulated), administred600 mg once daily for 7 days

| | |
|--|--------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Plaquenil |
| Investigational medicinal product code | P01BA02 |
| Other name | Hydroxychloroquine |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

tablets contains 200 mg

Patients received 600 mg daily

| | |
|------------------|-------------|
| Arm title | Baricitinib |
|------------------|-------------|

Arm description:

Baricitinib (Olumiant) (capsulated), administred 4 mg daily for 7 days

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | Olumiant |
| Investigational medicinal product code | L04AA37 |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablets of 2 mg

2 tablets (4 mg) daily for 7 days

| | |
|--|----------|
| Arm title | Placebo |
| Arm description: | |
| Placebo tablet containing glucosemonohydrat (capsulated) administred once daily for 7 days | |
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 3 capsulated placebo tablets once daily for 7 days | |

| Number of subjects in period 1 | Hydroxychloroquin | Baricitinib | Placebo |
|--------------------------------|-------------------|-------------|---------|
| Started | 1 | 4 | 1 |
| Completed | 0 | 4 | 1 |
| Not completed | 1 | 0 | 0 |
| Adverse event, non-fatal | 1 | - | - |

Baseline characteristics

Reporting groups

| Reporting group title | Inclusion |
|--------------------------------|-----------|
| Reporting group description: - | |

| Reporting group values | Inclusion | Total | |
|---|-----------|-------|--|
| Number of subjects | 6 | 6 | |
| Age categorical | | | |
| Participant age | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 3 | 3 | |
| From 65-84 years | 2 | 2 | |
| 85 years and over | 1 | 1 | |
| Gender categorical | | | |
| 3/6 (50%) participants were female and 3/6 (50%) were male. | | | |
| Units: Subjects | | | |
| Female | 3 | 3 | |
| Male | 3 | 3 | |
| Comorbidity | | | |
| Number of comorbidities at the time of inclusion | | | |
| Units: Subjects | | | |
| Cardiac disease | 0 | 0 | |
| Cerebral disease | 0 | 0 | |
| Peripheral vascular disease | 0 | 0 | |
| Nephrological disease | 0 | 0 | |
| Chronic Obstructive Lung Disease (COLD) | 0 | 0 | |
| Asthma | 0 | 0 | |
| Diabetes | 1 | 1 | |
| Cancer | 0 | 0 | |
| Connective tissue disease | 0 | 0 | |
| Ulcer | 0 | 0 | |
| Liver disease | 0 | 0 | |
| Other | 0 | 0 | |
| None | 5 | 5 | |
| Ethnicity | | | |
| Ethnicity | | | |
| Units: Subjects | | | |
| Caucasian | 3 | 3 | |
| Middle East | 3 | 3 | |
| Asian | 0 | 0 | |

| | | | |
|---|---|---|--|
| Latin American | 0 | 0 | |
| Smoking | | | |
| Smoking at baseline | | | |
| Units: Subjects | | | |
| Yes | 0 | 0 | |
| No | 4 | 4 | |
| Previous | 2 | 2 | |
| Close contact to COVID-19 case | | | |
| Close contact to COVID-19 case prior to admission | | | |
| Units: Subjects | | | |
| Yes | 4 | 4 | |
| No | 2 | 2 | |
| Location of transmission | | | |
| Suspected location of transmission | | | |
| Units: Subjects | | | |
| Home | 2 | 2 | |
| Travel | 0 | 0 | |
| Workplace | 1 | 1 | |
| Unknown | 3 | 3 | |
| Other | 0 | 0 | |
| Nursing home resident | | | |
| Units: Subjects | | | |
| Yes | 0 | 0 | |
| No | 6 | 6 | |
| Functional level | | | |
| Functional level prior to admission | | | |
| Units: Subjects | | | |
| Self-reliant | 6 | 6 | |
| Home Help | 0 | 0 | |
| Need of home nursing support | 0 | 0 | |
| Dyspnea | | | |
| Dyspnea as debut COVID-19 symptom | | | |
| Units: Subjects | | | |
| Yes | 4 | 4 | |
| No | 2 | 2 | |
| Dry Coughing | | | |
| Dry Coughing as debut COVID-19 symptom | | | |
| Units: Subjects | | | |
| Yes | 4 | 4 | |
| No | 2 | 2 | |
| Coughing with sputum | | | |
| Coughing with sputumas debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 3 | 3 | |
| No | 3 | 3 | |
| Chest tightness | | | |
| Chest tightness as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 0 | 0 | |
| No | 6 | 6 | |
| Fever | | | |

| | | | |
|--|-----------|---|--|
| Fever as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 6 | 6 | |
| No | 0 | 0 | |
| Sore throat | | | |
| Sore throat as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 1 | 1 | |
| No | 5 | 5 | |
| Muscle and/or joint pain | | | |
| Muscle and/or joint pain as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 2 | 2 | |
| No | 4 | 4 | |
| Headache | | | |
| Headache as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 2 | 2 | |
| No | 4 | 4 | |
| Changes in smell and/or taste | | | |
| Changes in smell and/or taste as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 1 | 1 | |
| No | 5 | 5 | |
| Nausea/vomit | | | |
| Nausea as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 2 | 2 | |
| No | 4 | 4 | |
| Diarrhea | | | |
| Diarrhea as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 2 | 2 | |
| No | 4 | 4 | |
| Erythema | | | |
| Erythema as debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 0 | 0 | |
| No | 6 | 6 | |
| Other debut symptoms | | | |
| Other debut COVID-19 symptom? | | | |
| Units: Subjects | | | |
| Yes | 1 | 1 | |
| No | 5 | 5 | |
| Weight | | | |
| Weight at baseline | | | |
| Units: kg | | | |
| arithmetic mean | 86 | | |
| full range (min-max) | 66 to 157 | - | |
| Height | | | |
| Height at baseline | | | |

| | | | |
|---------------------------------------|------------|---|--|
| Units: cm | | | |
| arithmetic mean | 172 | | |
| full range (min-max) | 157 to 183 | - | |
| Symptom debut | | | |
| Days with symptoms prior to admission | | | |
| Units: days | | | |
| arithmetic mean | 7 | | |
| full range (min-max) | 3 to 11 | - | |

End points

End points reporting groups

| | |
|------------------------------|---|
| Reporting group title | Hydroxychloroquin |
| Reporting group description: | Hydroxychloroquine (Plaquenil) (capsulated), administered 600 mg once daily for 7 days |
| Reporting group title | Baricitinib |
| Reporting group description: | Baricitinib (Olumiant) (capsulated), administered 4 mg daily for 7 days |
| Reporting group title | Placebo |
| Reporting group description: | Placebo tablet containing glucosemonohydrat (capsulated) administered once daily for 7 days |

Primary: All-cause mortality or need of invasive mechanical ventilation up to 28 days

| | |
|------------------------|--|
| End point title | All-cause mortality or need of invasive mechanical ventilation up to 28 days |
| End point description: | |
| End point type | Primary |
| End point timeframe: | 28 days |

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: Subjects | 0 | 0 | 1 | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Placebo |
| Comparison groups | Hydroxychloroquin v Baricitinib v Placebo |
| Number of subjects included in analysis | 6 |
| Analysis specification | Post-hoc |
| Analysis type | other ^[1] |
| P-value | = 0 |
| Method | None |
| Parameter estimate | none |

Notes:

[1] - One patient died during the study. No causality between IMP and mortality was suspected. The patient who died received placebo.

Secondary: Frequency of adverse events

| | |
|------------------------|-----------------------------|
| End point title | Frequency of adverse events |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 90 days | |

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: number of AE | 4 | 10 | 2 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of severe adverse events

| | |
|------------------------|------------------------------------|
| End point title | Frequency of severe adverse events |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 90 days | |

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: number of SAE | 1 | 0 | 1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ventilator-free days to day 28

| | |
|------------------------|--------------------------------|
| End point title | Ventilator-free days to day 28 |
| End point description: | |
| End point type | Secondary |

End point timeframe:

28 days

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: days | 1 | 4 | 1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Organ failure-free days to day 28

End point title Organ failure-free days to day 28

End point description:

End point type Secondary

End point timeframe:

28 days

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: days | 1 | 4 | 1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of ICU stay

End point title Duration of ICU stay

End point description:

End point type Secondary

End point timeframe:

90 days

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: days | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mortality rate

| | |
|------------------------|----------------|
| End point title | Mortality rate |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 90 days | |

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: subjects | 0 | 0 | 1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Length of hospital stay

| | |
|------------------------|-------------------------|
| End point title | Length of hospital stay |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 90 days | |

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: days | 6 | 10 | 7 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of supplemental oxygen

| | |
|-----------------|---------------------------------|
| End point title | Duration of supplemental oxygen |
|-----------------|---------------------------------|

End point description:

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

End point timeframe:

90 days

| End point values | Hydroxychloroquin | Baricitinib | Placebo | |
|-----------------------------|-------------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 1 | 4 | 1 | |
| Units: days | 5 | 6 | 7 | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

90 days

Adverse event reporting additional description:

Adverse events were collected by reviewing medical records during hospitalizations and by telephone follow-up at day 7, 14, 28 and 90.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 10.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------------|
| Reporting group title | Hydroxychloroquin |
|-----------------------|-------------------|

Reporting group description:

Hydroxychloroquine (Plaquenil) (capsulated), administered 600 mg once daily for 7 days

| | |
|-----------------------|-------------|
| Reporting group title | Baricitinib |
|-----------------------|-------------|

Reporting group description:

Baricitinib (Olmiant) (capsulated), administered 4 mg daily for 7 days

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Placebo tablet containing glucosemonohydrat (capsulated) administered once daily for 7 days

| Serious adverse events | Hydroxychloroquin | Baricitinib | Placebo |
|---|-------------------|---------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 4 (0.00%) | 1 / 1 (100.00%) |
| number of deaths (all causes) | 0 | 0 | 1 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Cardiac disorders | | | |
| QTc-prolongation | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 4 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Death | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 4 (0.00%) | 1 / 1 (100.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |

| Non-serious adverse events | Hydroxychloroquin | Baricitinib | Placebo |
|---|--|--|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 1 / 1 (100.00%) | 3 / 4 (75.00%) | 1 / 1 (100.00%) |
| Cardiac disorders EKG changes subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 0 / 4 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Nervous system disorders Paraesthesia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 4 (25.00%) 1 | 0 / 1 (0.00%) 0 |
| Blood and lymphatic system disorders Hyperkalaemia subjects affected / exposed occurrences (all) Hypokalaemia subjects affected / exposed occurrences (all) Thrombocytosis subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 | 1 / 4 (25.00%) 1 0 / 4 (0.00%) 0 1 / 4 (25.00%) 1 | 0 / 1 (0.00%) 0 1 / 1 (100.00%) 1 0 / 1 (0.00%) 0 |
| General disorders and administration site conditions Headache subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 4 (25.00%) 1 | 0 / 1 (0.00%) 0 |
| Gastrointestinal disorders Hyperamylasaemia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 4 (25.00%) 1 | 0 / 1 (0.00%) 0 |
| Hepatobiliary disorders Increased transaminases subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 4 (25.00%) 1 | 0 / 1 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders pulmonary edema | Additional description: High pressure pulmonary edema | | |

| | | | |
|--|--|--------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 4 (0.00%) 0 | 1 / 1 (100.00%) 1 |
| Skin and subcutaneous tissue disorders | | | |
| Skin rash | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 4 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hair loss | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 4 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychiatric disorders | | | |
| Memory impairment | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 1 / 4 (25.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Renal and urinary disorders | | | |
| hematuria | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 4 (25.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nephropathy | Additional description: Worsening of chronic nephropathy | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 4 (25.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infections and infestations | | | |
| Fever | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 4 (25.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|--------------|------------------------------------|
| 09 June 2020 | The hydroxychloroquine arm closed. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|--------------|---|--------------|
| 17 June 2020 | Pre-mature termination of the study. The trial continues as a non-drug trial with convalescence plasma. | - |

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The trial is terminated pre-maturely. Only 6 patients were included (1500 predicted) therefore results are not analysed.

Notes: