Data entry in the COVID STEROID trial

Place in Site Master File #9a,iv

Log on

Go to http://www.cric.nu/covid-steroid-trial/.

Here you will find all trial documents and a link to the electronic case report form (eCRF).

Click the 'Screen, randomise, and enter data'.

Low dose hydrocortisone in patients with COVID-19 and severe hypoxia

– the COVID STEROID trial

HOTLINE: +45 35 45 72 37

Screen, randomise, and enter data

Trial documents

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Place in Site Master File #9a,iv

Enter username (e-mail) and password. The first time you log on, please use the password 12345678.

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Place in Site Master File #9a,iv

User access to the eCRF

Unblinded staff can screen, randomise, view allocation and enter data in the baseline form, administered trial medication form, consent form and withdrawal form. They can view but not edit data entered in dayforms, follow-up forms, and discharge and re-admission form.

Blinded staff can enter data in the baseline form, dayforms, follow up forms, discharge and re-admission form, consent form and withdrawal form. They can view but not edit data entered in the screening form and administered trial medication form. Blinded staff cannot view the allocation.

If you try to access forms you do not have access to, the system will lead you back to the front page automatically.

To view allocation for unblinded staff

Click 'Allocation View'.

ng click here: Go to Patient Screening   For Site overview click here: Site Overview

Allocation View

Name	NIN	Enrolment Date ▼	Screening	Baseline	Consent form	Day form	Administered trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions
		08-06-2020	☑										Click here to enter data
		30-05-2020		☑		x10	☑						Click here to enter data

The allocation list will appear in a new window.

Allocation Overview for site DK01

Click here to get back to Front page

Participant ID	NIN	Participant name	Randomised by	Timestamp	Allocation

Overview of the eCRF

On the front page, you will see the participant list.

| Front page | Change Site | Log Out | Participant ID | Go |

Participant List for DK01 Test site

For Screening click here: Go to Patient Screening   **For Site overview click here:** Site Overview

Randomisations and Transfers View | Remove Form Lock | Direct Transfer/Readmission | Site User Handling

Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Consent form	Day form	Administered trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions
DK01010	Messi	D1234152626	27-04-2020	✅	🟧	🟧	🟧 x14	✅	🟧	🟧	📘	📘	🟧	Click here to enter data
DK01009	Carol Baskin	D1010505555	27-04-2020	✅	🟧	✅	🟧 x14	🟧	🗓️	🟧	📘	📘	📘	Click here to enter data
DK01008	Janus Tester 1	D9878888876	24-04-2020	✅	✅	🟧	🟧 x14	🟧	🗓️	🟧	📘	📘	🗓️	Click here to enter data
DK01007	[Name unknown]	D1323134444	23-04-2020	✅	🟧	🟧	🟧 x14	🟧	🗓️	🟧	📘	📘	🗓️	Click here to enter data
DK01006	Sulejma	D7766554433	23-04-2020	✅	🟧	🟧	🟧 x14	🟧	🟧	🟧	📘	📘	🗓️	Click here to enter data
DK01005	Hanne	D1881919199	21-04-2020	✅	🟧	🟧	🟧 x14	🟧	🗓️	🟧	📘	📘	🗓️	Click here to enter data
DK01003	Mads	D1234567123	18-04-2020	✅	🟧	🟧	🟧 x14	🟧	🗓️	🟧	📘	📘	🗓️	Click here to enter data
DK01002	Børge	D0609946666	18-04-2020	✅	🟧	🟧	🟧 x14	🟧	🗓️	🟧	📘	📘	🗓️	Click here to enter data

Results 1 - 8 of 8

The screenshot is from a demo version of the eCRF

The participant list contains participant ID, name, national identification number (NIN) and enrolment date. It also contains an overview of all forms for each participant. The colours of the icons indicate the status of the form:

📘 Data entry not possible

🗓️ Form scheduled, data entry possible if necessary (withdrawal, discharge)

🟧 Data entry possible/started but incomplete

✅ Data entry completed

New dayforms will be generated daily the first 14 days. The 'Administered Trial Medication' form contains 8 different forms to be filled out every day for the first 7 full days after randomisation.

At the top of the webpage you can:

1. Return to front page
2. Change Site
3. Log out

1   **2**   **3**

Front page | Change Site | Log Out   Participant ID | Go
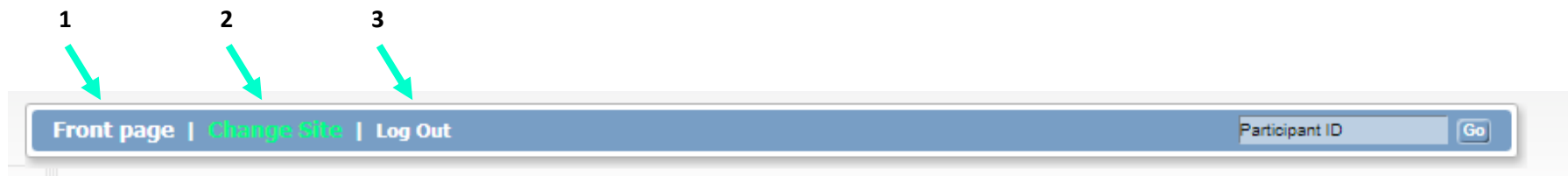
Change site

Here you can get an overview of all sites that you have access to. Please access the transfer site if a participant has been transferred from one site to another, and all forms have <u>not</u> been completed from the original site. Once all forms are completed, the participant will automatically appear at the new site.

COVID STEROID

- ▷ ○ DK01 Test site [DK01] (Clinical Research Coordinator)
- ▷ ◉ DK02 Test site [DK02] (Clinical Research Coordinator)
- ▷ ○ Transfer [DK01] to [DK02] [Transfer [DK01] to [DK02]] (Clinical Research Coordinator)

Data entry in the COVID STEROID trial

Place in Site Master File #9a,iv

From the front page, you can access:

1. Patient screening
2. Site overview
3. Data entry for each participant

Site overview

Here you can get an overview of all included and excluded patients.

1. Scroll to select site
2. List of included patients at site
3. List of excluded patients at site

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+45 35 45 72 37 • covid-steroid@cric.nu • www.cric.nu/covid-steroid-trial/ • v.1.0

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COVID STEROID

1

Site Overview

[DK02 ▼]   Click here to get back to Front page   Click here to scroll to Exclusions

- Click "Participant ID" or "Name" to highlight row
- Hover on Form status symbol to see start date and end date
- Click Form status symbol to enter form data

2

Participant ID	Name	NIN	Randomisation Date	Screening last updated by	Screening	Baseline	Consent form	DF 1	DF 2	DF 3	DF 4	DF 5	DF 6	DF 7	DF 8	DF 9	DF 10	DF 11	DF 12	DF 13	DF 14	DF 15
DK02084	Joseph Maldonado	D2504201234	24-04-2020 21:10	jaschw@rm.dk	☑	☑	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	
DK02083	John Doe	D1234567894	23-04-2020 10:47	ali.akil.al-alak.03@regionh.dk	☑	☑	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	
DK02080	POUL TESTMAN	D2907882918	22-04-2020 17:30	chrtoe@rm.dk	☑	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	
DK02078	Anders Andersen	D1111111111	22-04-2020 12:05	jeppe_jensen@msn.com	☑	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	
DK02075	Yda	D0304401365	22-04-2020 08:52	birte.najbjerg.norby@rsyd.dk	☑	☑	☑	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	
DK02069	Jørgen	D5684215681	21-04-2020 10:57	caroline.loekke.bjerregaard@regionh.dk	☑	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	
DK02066	Sofie Sofiesen	D1234561234	20-04-2020 14:45	hanne.irene.jensen@rsyd.dk	☑	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	▤	

3

Screening Failures

Click here to get back to Front page   Click here to scroll to top

Participant ID	Birthday (DK sites only)	Screening Failure Date	Screening last updated by
DK02076	D1234567891 [not a CPR value]	22-04-2020 09:15	johanmikkelsen1@gmail.com

Data entry

To enter data, click on 'Click here to enter data' on the participant list.

Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Consent form	Day form	Administered trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions
DK02084	Joseph Maldonado	D2504201234	24-04-2020	☑	☑	▤	▤ x14	☑	▦	▤	▥	▥	▤	Click here to enter data
DK02083	John Doe	D1234567894	23-04-2020	☑	☑	▤	▤ x14	▤	▦	▤	▥	▥	▦	Click here to enter data
DK02080	POUL TESTMAN	D2907882918	22-04-2020	☑	▤	▤	▤ x14	▤	▦	▤	▥	▥	▦	Click here to enter data

Data entry in the COVID STEROID trial

Place in Site Master File #9a,iv

To enter data for the first time, click 'Click here to enter data'. To edit, click 'Administrative edit'. To view data, click 'Click here to view data'.

Baseline	24-04-2020 21:10		☑	**Administrative edit**	Click here to view data (read only)	24-04-2020 (jaschw@rm.dk)
Consent form	24-04-2020 21:10		🗒	Click here to enter data	Click here to view data (read only)	24-04-2020 (jaschw@rm.dk)
Administered trial medication	24-04-2020 21:10		📄	Click here to enter data	Click here to view data (read only)	
Discharge and readmission	24-04-2020 21:10		📄	Click here to enter data	Click here to view data (read only)	
Withdrawal	24-04-2020 21:10		🗒	Click here to enter data	Click here to view data (read only)	()
Day form (1)	24-04-2020 21:10	25-04-2020 05:59	🗒	Click here to enter data	Click here to view data (read only)	()
Screening	24-04-2020 21:08	24-04-2020 21:10	☑	**Administrative edit**	Click here to view data (read only)	24-04-2020 (jaschw@rm.dk)

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Place in Site Master File #9a,iv

COVID STEROID

To get further information about each domain to be filled in the forms, hold the mouse over the [info] box.

BL1	Sex?	● Male [info]
		○ Female
BL2	Hospital admission date?	24-04-2020 ⌨ (dd-mm-yyyy) [info]
BL3	Number of days with symptoms before hospital admission?	5 ☐ Unobtainable [info]
BL4	Department at which the participant was included?	○ Emergency department or directly from the pre-hospital setting
		○ Hospital ward
		○ Intermediate care unit
		● Intensive care unit

Co-morbidities prior to hospital admission

BL5	History of ischemic heart disease or heart failure?	○ Yes [info]
		● No
BL6	History of chronic hypertension?	● Yes [info]
		○ No
BL7	Chronic pulmonary disease?	○ Yes [info]
		● No
BL8	Diabetes mellitus?	○ Yes [info]
		● No

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Place in Site Master File #9a,iv

When the form has been completed, click 'Submit form'. If data have been entered, but the form is not completed, click 'Save'. If you do not want to save the entered data, click 'Exit (no save)'.

Please make sure that the form has been submitted (and not just saved) when you have completed data entry.

Specific forms in the eCRF

Screening form

To calculate the oxygen supplementation through an open system, please use the provided converter if a mixture of pure oxygen and atmospheric air is used.

Baseline form

This is the most comprehensive form. Please note:

'Hospital admission date': Please enter the date of admission to the first hospital during current admission

'Agents with potential anti-inflammatory action during current hospital admission?': Enter yes, if given before first trial medication administration (also if this is after randomisation). Not including inhalation or topical drugs.

'Use of any drug with potential antiviral activity during current hospital admission?': Enter yes, if given before first trial medication administration (also if this is after randomisation). Not including topical drugs.

Administered trial medication form

Please note: The start and end time of each form corresponds to the start and end time of each day in the electronic medical journals (06.00 am – 05.59 am)

- Day 1 starts at the date and time of randomisation and ends at 05.59 am.

- Day 2-7 start at 06.00 am and end at 05.59 am.
- Day 8 start at 06.00 am and ends at the time of randomisation minus 1 minute.

'Did the patient receive at least 50% of the planned volume on this day?': The data source for the administered volume is preferably the electronic or paper medical journal. If this is not noted in the medical journal, this can also be confirmed by daily visual inspection of trial medication by trial staff.

Discharge and readmission form

Discharge the participant when the participant is transferred to another hospital/ward, home or if the participant dies. If the participant is registered as dead, the generation of dayforms and follow-up forms will stop. Save and exit the form.

Re-enter and readmit the participant if the participant is transferred to another hospital/ward. This is done by clicking 'Add'. Remember to apply site ID if the patient is transferred to another site participating in the COVID STEROID trial. Discharge and re-admission can be filled out as many times as needed within 90 days of randomisation or until death, but remember you must exit and re-enter the form every time you wish to add a new row.

Remember to complete all forms when transferring a participant to another trial site. The participant will appear in the transfer site until this is done. Remember to inform the receiving site about the transferal.

Withdrawal

The participant can be withdrawn for the following reasons:

- Clinical decision in conjunction with coordinating investigator
- Withdrawal from active therapy
- SAR/SUSAR

- Consent not given or withdrawn
- Patient is subject to compulsory hospitalisation

Remember to fill out the withdrawal form if the participant is withdrawn.

Data registration will continue if the participant is withdrawn due to clinical decision in conjunction with coordinating investigator, withdrawal from active therapy, SAR/SUSAR or if the participant is subject to compulsory hospitalisation.

If consent is not given or withdrawn, remember to ask for permission to continue data registration.

Dayforms

Dayforms will be generated automatically the first 14 days after randomisation. Registration of major protocol violations (use of open-label corticosteroids) will be registered during the first 8 days after randomisation (the same period as trial medication is administered).

If the participant dies and is discharged to 'Dead', the generation of dayforms will stop automatically.

Follow-up forms

Follow-up forms will be generated automatically 28 days, 90 days and 1 year after randomisation.

If the participant dies and is discharged to 'Dead', the generation of follow-up forms will stop automatically.

Consent form

Co-enrollment may be noted in the consent form.

Click 'Oral and written trial information given', when the trial guardian/next of kin/participant have been informed orally and have received written information about the trial.

Remember to upload the consent form electronically when this has been signed by the trial guardian/next of kin/participant.

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Place in Site Master File #9a,iv

COVID
STEROID

| C0 | Co-enrollment | CLASSIC |

Upload consent form

| C1a | Oral and written trial information given to Trial guardian 1 | ☑ Oral and written trial information given |

| C1a1 | Date when information was first given | 09-06-2020 | | If trial guardian 1 was initially informed orally, please enter the date of oral information and consent |

| C1b | Trial guardian 1 consent form | | Click to upload file |

| C1c | Optional comment | Informed by MWP |