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Log on

Go to <u>http://www.cric.nu/covid-steroid-2/</u>. Here you will find all trial documents and a link to the electronic case report form (eCRF).

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



Higher vs. Lower Doses of Dexamethasone in Patients with COVID-19

and Severe Hypoxia: the COVID STEROID 2 trial

HOTLINE: +45 35 45 72 37



Screen, randomise, and enter data



Trial documents

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



The screenshot is from a demo version of the eCRF

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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 screen, randomise, enter data in the baseline form, dayforms, follow up forms, discharge and re-admission form, consent form and withdrawal 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													
100 Show More 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						ଖ୍ର				<u>열</u>	Click here to enter data
		30-05-2020				🔁 x10		2				(11)	Click here to enter data

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The allocation list will appear in a new window.

					>
Participant ID	NIN	Participant name	Randomised by	Timestamp	Allocation
DK01005	D1234123412	YS	warrer	13-08-2020 08:34:31	Dexamethasone 6 mg
IN01001	010146IN01001		warrer	13-08-2020 13:08:57	Dexamethasone 6 mg
IN01002	010186IN01001		warrer	14-08-2020 15:54:36	Dexamethasone 6 mg
DK01004	D1818199911	Ursula	mariewpetersen@gmail.com	12-08-2020 09:29:09	Dexamethasone 12 mg

Overview of the eCRF

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

t page Cha	nge Sile Log Out					Participant II	D	Go						
articipant List í	for DK01 Test site													
For Scree	ning click here:	Go to Patient Screen	ing For Site o	overview	click he	ere: Site Ov	erview							
									Randomisation	is and Transfers Vie	w Remove Form	n Lock Direct T	Fransfer/Readr	nission Site User Handl
	100 🔻 Show More													
I∢ I ↓ ↓ ↓ Participant ID ↓	1 100 V Show More	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
			Enrolment Date 🗸	Screening	Baseline	Consent form	Day form			28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions
			Enrolment Date -	Screening	Baseline	Consent form	Day form			28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions Click here to enter data
'articipant ID 🔻	Name	NIN						trial medication	readmission			1 year follow-up		
Yarticipant ID ▼ DK01010	Name	NIN D1234152626	27-04-2020				×14	trial medication	readmission					Click here to enter data
Participant ID → DK01010 DK01009	Name Messi Carol Baskin	NIN D1234152626 D1010505555	27-04-2020 27-04-2020				X14 X14	trial medication	readmission					Click here to enter data Click here to enter data
Participant ID → DK01010 DK01009 DK01008	Name Messi Carol Baskin Janus Tester 1	NIN D1234152626 D1010505555 D9878888876	27-04-2020 27-04-2020 24-04-2020				x14 x14 x14 x14	trial medication	readmission ତା ବୁମ୍ବ					Click here to enter data Click here to enter data Click here to enter data
Varticipant ID - DK01010 DK01009 DK01008 DK01007	Name Messi Carol Baskin Janus Tester 1 [Name unknown]	NIN D1234152626 D1010505555 D9878888876 D1323134444	27-04-2020 27-04-2020 24-04-2020 23-04-2020				×14 ×14 ×14 ×14 ×14	trial medication	readmission ି ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ ୁ				2 2 2 2 2 2 2 2 2	Click here to enter data Click here to enter data Click here to enter data Click here to enter data
Participant ID → DK01010 DK01009 DK01008 DK01007 DK01006	Name Messi Carol Baskin Janus Tester 1 [Name unknown] Sulejma	NIN D1234152626 D1010505555 D9878888876 D1323134444 D7766554433	27-04-2020 27-04-2020 24-04-2020 23-04-2020 23-04-2020				x14 x14 x14 x14 x14 x14 x14	trial medication	readmission N 인 인 인 N				2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Click here to enter data Click here to enter data Click here to enter data Click here to enter data Click here to enter data

The screenshot is from a demo version of the eCRF

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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

At the top of the webpage you can:

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



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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)	
• OK02 Test site [DK02] (Clinical Research Coordinator)	
Transfer [DK01] to [DK02] [Transfer [DK01] to [DK02]] (Clinical Research Coordinat	or

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From the front page, you can access:

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

	-	1				2								
t page <mark>Cha</mark>	nge Sille Log Out					Participant II	D	Go						
articipant List f	for DK01 Test site												3	
For Screer	ning click here:	Go to Patient Screen	ing For Site o	overview	click he	Site Ove	erview		Dendensiesties	ns and Transfers Vie	Derror Ferr	Leek Direct T		
									Randomisation	is and transfers vie	Remove Form	TLOCK Direct 1	ransfer/Readr	mision Site User Handlin
	1 100 T Show More	NIN	Enrolment Date 🕶	Screening	Baseline	Consent form	Day form	Administered trial medication	Randomisation	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	n sion Site User Handlin
articipant ID 👻	Name							trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions
articipant ID 🔻 K01010	Name Messi	D1234152626	27-04-2020				x14	trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions Click here to enter data
articipant ID ↓ 0K01010 0K01009	Name Messi Carol Baskin	D1234152626 D1010505555	27-04-2020 27-04-2020				×14	trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions Click here to enter data Click here to enter data
articipant ID ▼ 0K01010 0K01009 0K01008	Name Messi Carol Baskin Janus Tester 1	D1234152626 D1010505555 D9878888876	27-04-2020 27-04-2020 24-04-2020				x14 x14 x14 x14	trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions Click here to enter data Click here to enter data Click here to enter data
Karticipant ID ▼ DK01010 DK01009 DK01008 DK01007	Name Messi Carol Baskin Janus Tester 1 [Name unknown]	D1234152626 D1010505555 D9878888876 D1323134444	27-04-2020 27-04-2020 24-04-2020 23-04-2020				×14 ×14 ×14 ×14 ×14	trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions Click here to enter data Click here to enter data
Participant ID V DK01010 DK01009 DK01008 DK01007	Name Messi Carol Baskin Janus Tester 1	D1234152626 D1010505555 D9878888876	27-04-2020 27-04-2020 24-04-2020				x14 x14 x14 x14 x14 x14 x14 x14	trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions Click here to enter data Click here to enter data Click here to enter data
I I I I I I I I I I I I I I I I I I I	Name Messi Carol Baskin Janus Tester 1 [Name unknown]	D1234152626 D1010505555 D9878888876 D1323134444	27-04-2020 27-04-2020 24-04-2020 23-04-2020				×14 ×14 ×14 ×14 ×14 ×14 ×14 ×14	trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions Click here to enter data Click here to enter data Click here to enter data Click here to enter data
Participant ID	Name Messi Carol Baskin Janus Tester 1 [Name unknown] Sulejma	D1234152626 D1010505555 D9878888876 D1323134444 D7766554433	27-04-2020 27-04-2020 24-04-2020 23-04-2020 23-04-2020				x14 x14 x14 x14 x14 x14 x14 x14	trial medication	Discharge and readmission	28 days follow-up	90 days follow-up	1 year follow-up	Withdrawal	Actions Click here to enter data Click here to enter data Click here to enter data Click here to enter data Click here to enter data

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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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

Participant ID	Name	NIN	Randomisation Date	Screening last updated by	Screening	Baseline	Consent form	DF 1	DF 2)F 6				DF 12	DF 14	
DK02084	Joseph Maldonado	D2504201234	24-04-2020 21:10	jaschw@rm.dk							1							
DK02083	John Doe	D1234567894	23-04-2020 10:47	ali.akil.al-alak.03@regionh.dk							8 (
DK02080	POUL TESTMAN	D2907882918	22-04-2020 17:30	chrtoe@rm.dk							1			Ν				
DK02078	Anders Andersen	D111111111	22-04-2020 12:05	jeppe_jensen@msn.com							1							
DK02075	Yda	D0304401365	22-04-2020 08:52	birte.najbjerg.norby@rsyd.dk							1							
DK02069	Jørgen	D5684215681	21-04-2020 10:57	caroline.loekke.bjerregaard@regionh.dk							1							
DK02066	Sofie Sofiesen	D1234561234	20-04-2020 14:45	hanne.irene.jensen@rsyd.dk							1							



2

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

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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			8	🔁 x14		(<u>)</u>					Click here to enter data 🗡
DK02083	John Doe	D1234567894	23-04-2020				🔁 x14		<u>(1</u>)				(2)	Click here to enter data
DK02080	POUL TESTMAN	D2907882918	22-04-2020			8	🔁 x14		(11)				(2)	Click here to enter data
				0	(T)		-	-	-	-	(3)	-		

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'.

1	1	1			
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)	0
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)	0
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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To get further information about each domain to be filled in the forms, hold the mouse over the [info] box.

8L1	Sex?	Male [info] Female
81.2	Hospital admission date?	03-08-2020 (dd-mm-yyyy) [info]
BL3	Number of days with symptoms before hospital admission?	4 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-m	orbidities prior to hospital admission
BL5	History of ischemic heart disease or heart failure?	● Yes [info] ○ No
BL6	Immunosuppressive therapy within the last 3 months?	○ Yes [info] No
BL7	Chronic pulmonary disease?	 Yes [info] No
BL8	Diabetes mellitus?	<pre> Yes [info] No </pre>

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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

National identification number:

For Danish sites, please type Danish National identification number:

		SCREENING FORM	
			Support: mail or +45 3545 7237
		Patient Identification	
S1	National identification number		[info]

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For international sites, please type in date of birth or year of birth according to local regulations.

SCREENING F	ORM
Su	pport: mail or +45 3545 7237
Patient Identif	ication
St National identification number	230245/N01001 🏴 [info]
Date of birth 230245 Note ID (ddmmyy)	IN01 🍽 Serial 001 🏴

SCREENING FORM			
Support: mail or +45 3545 7237			
Patient Identification			
S1. National identification number 010145/N01001 🕨 [info]			
Year of birth (yyyy) 1945 🕅 Site ID ///// 🍽 Serial 001 🕅			

This will automictically generate a substitute national identification number in S1. Use this number to identify the patient on a separate list with further details about the patient according to local regulations.

Place in Site Master File #9a,iv



SCREENING FORM				
	Support: mail or +45 3545 7237			
Patient Identification				
S1. National identification number	230245/N01001 🍽 [info]			
Date of birth (ddmmyy)	Site ID /NO1 🍽 Serial 001 🕅			

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

	Inclusion criteria				
S2	Is the patient \geq 18 years old?	💿 Yes 💿 No 🏴			
S3	Does the patient have documented COVID-19?	● Yes ─ No 🏴 [info]			
S4	Oxygen supplementation through an open system with an oxygen flow of at least 10 L/min?	● Yes ● No 🏴 [info]			
	Note: Round to nearest whole number. If mixture of pure oxygen and atmospheric air is used, use this converter to calculate supplemental oxygen flow.				

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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 <u>first</u> 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 <u>first</u> trial medication administration (also if this is after randomisation). Not including topical drugs.

Administered trial medication (ATM) form

The number of ATM forms depend on the number of consecutive days with corticosteroid treatment before randomisation. The maximum number of ATM forms is 10 (for patients with no preceding corticosteroid treatment) and the minimum number is 6 (for patients with 4 consecutive days of corticosteroid treatment before randomisation). Patients who have received corticosteroids for 5 consecutive days or more will be excluded from the trial. The number of ATM forms is determined by subtracting the number of days with corticosteroids before randomisation from 10:

- 0 days of corticosteroid treatment before randomisation: 10 ATM forms
- 1 days of corticosteroid treatment before randomisation: 9 ATM forms
- 2 days of corticosteroid treatment before randomisation: 8 ATM forms
- 3 days of corticosteroid treatment before randomisation: 7 ATM forms
- 4 days of corticosteroid treatment before randomisation: 6 ATM forms

The number of ATMs form is generated automatically.

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.

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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.

Title: Discharge and readmission						
ructions:						
			DISCHARGE AND RI	FADMISSION FORM		
			DISCHARGE AND R			
					Support: n	ail or +45 3545 72
			1			1
te of hospital readmission	Time of hospital readmission	Date of hospital discharge	Time of hospital discharge	Patient discharged to	Has the patient been enrolled in other interventional trials	Patient transferred
(dd-mm-yyyy)	(hh:mm, 24 hours format)	(dd-mm-yyyy)	(hh:mm, 24 hours format)	[info]	during this hospital admission	to site Id
				Other hospital/ward participating in the COVID STEROID trial		
				Other hospital/ward not participating in the COVID STEROID trial	Yes	
n 🔲	he he	25-05-2020 🏴	23:38	Home	No	DK01
				Dead	(Pu	
				99		
				Other hospital/ward participating in the COVID STEROID trial	~	
05-2020	23:38	e 🗐 🕅	100	Other hospital/ward not participating in the COVID STEROID trial		DK01
00-2020	23.30			Home	No No	DKUI
				Dead	(0	
d		1		s		

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

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- 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 up to 10 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 180 days after randomisation.

If the participant dies and is discharged to 'Dead', the remaining follow-up forms will be filled out automatically.

Consent form

Co-enrolment 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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C0	Co-enrollment	CLASSIC			
	Upload consent form				
Cla	Oral and written trial information given to Trial guardian 1	Oral and written trial information given			
	Ctal 0 en information was first given	9-06-2020	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			