

CRASH-19

Aspirin, losartan & simvastatin in hospitalised COVID-19 patients: a multinational randomised open-label factorial trial

How to use the trial database: consent, data entry and randomisation

Adding a new patient

CRASH-19 Development Mode
Coronavirus Response - Active Support for Hospitalised COVID-19 patients.

Record Status Dashboard (all records)

Displayed below is a table listing all patients randomised at your associated site, and CRFs. To add a new participant, click the '+ Add new record' button.

To view any existing patient CRFs, click the coloured **circle button** under the column for that CRF.

To view the patient's record page, and all CRFs for that patient, click on the patient randomisation number.

Different lists of patients can be viewed using the drop-down menu next to 'Dashboard displayed'.

Note: Ensure the [Default dashboard] is selected to display the full list of patients and CRFs.

Dashboard displayed: [Default dashboard] ▼

Displaying record Page 1 of 1: "1" through "33" ▼ of 30 records

+ Add new record

Displaying: Instrument status only | Lock status only | All status types

| Randomisation number | Consent | Entry | Randomisation | Outcome | Serious Adverse Reaction | Query |
|----------------------|---------|-------|---------------|---------|--------------------------|-------|
| 1 | | | | | | |
| 2 | | | | | | |
| 3 | | | | | | |

Click '+ Add new record' to start entering the data for a new patient.

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

- The online consent form **MUST** be completed first.
- Click the grey radio button next to **Consent** to begin collecting data.

Click on the coloured radio buttons next to the name of the CRF to access that form. Where there are multiple forms (e.g. Consent, Entry, Randomisation, Outcome, Serious Adverse Reaction, Query), these can be viewed at the bottom of the page under 'Repeating instruments'. If additional forms (e.g. Follow-up Consent or follow-up Serious Adverse Reaction forms), click the '+' button next to the instrument name.

| Data Collection Instrument | Form Status Click on the radio buttons below to view/ add a form |
|----------------------------|---|
| Consent | <input checked="" type="radio"/> Complete this form first --> |
| Entry | <input type="radio"/> |
| Randomisation | <input type="radio"/> |
| Outcome | <input type="radio"/> |
| Serious Adverse Reaction | <input type="radio"/> |
| Query | <input type="radio"/> |

Adding a new patient and the consent form

Has a paper consent form been completed for this patient? Yes No

* must provide value



Has a paper consent form been completed for this patient? Yes No reset

* must provide value

Type of consent Patient Personal representative Professional representative reset

* must provide value

Language required for consent form English (Pakistan) Urdu English (Nigeria) Yoruba Hausa reset

* must provide value

For all patients, you must first indicate if consent has been obtained already on paper or not.

If it has, you do not need to enter this data. You may select Yes here and move on to collecting the entry data.

Where a paper consent form has not been completed and you need to collect consent electronically, Answer 'No' here, and an online PIS and consent form will open.

Translated copies of the PIS and consent form are also available online for use based on the language you select

Online consent form

Salmon Ahmed

[+ Add signature](#)

Yes
 No

reset

To add a signature, click '+Add signature' and a pop up will appear in which the relevant person can sign

Add signature

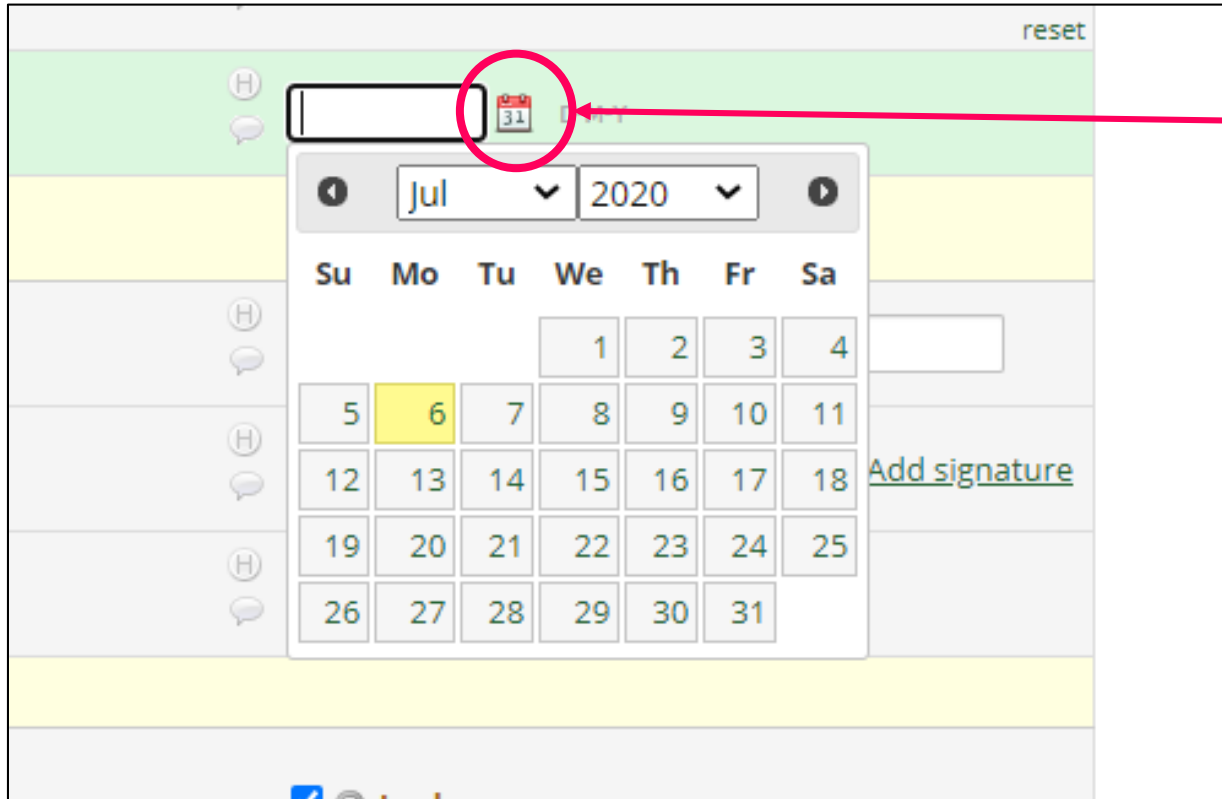
Participant Signature

SIGN HERE

Save signature [reset](#)

reset

Online consent form



The screenshot shows a web form with a date input field. A red circle highlights the calendar icon on the right side of the input field. A red arrow points from this icon to a text box on the right. The calendar pop-up is open, showing the month of July 2020. The date 6 is highlighted in yellow. The form includes a 'reset' button in the top right corner and an 'Add signature' link on the right side.

| Su | Mo | Tu | We | Th | Fr | Sa |
|----|----|----|----|----|----|----|
| | | | 1 | 2 | 3 | 4 |
| 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| 19 | 20 | 21 | 22 | 23 | 24 | 25 |
| 26 | 27 | 28 | 29 | 30 | 31 | |

The calendar function on the date fields can be used to select a date, rather than typing out the date

Online consent form

The screenshot shows an online consent form with the following sections:

- Signature of consent taker**: A text input field containing the handwritten signature "M.C." and a file upload confirmation "signature_2020-06-22_1427.png (0.01 MB)". Below the signature are "Remove file" and "Send-It" options.
- Date of consent**: A date input field containing "22-06-2020" and a calendar icon, with "D-M-Y" format indicated.
- Form Status**: A section containing two main buttons: "Save & Exit Form" (circled in red) and "Save & Go To Next Form" (with a dropdown arrow). Below these is a "-- Cancel --" button.

A red arrow points from the "Save & Exit Form" button to a text box containing the following instruction:

Complete all fields on the online consent form as applicable then click 'Save & Go To Next Form' to start entering the data on the Entry form

Entering entry form data

- *no contraindication to trial drugs*
- *not on mechanical ventilation*
- *not terminally ill / approaching end of life*

30. Eligible? Yes No reset

* must provide value

Please click 'Save & Go To Next Form' to randomise this patient.

Notes Expand

Form Status


Save & Exit Form Save & Go To Next Form -- Cancel --

Complete all fields on the online entry form then click 'Save & Go To Next Form' to proceed to the randomisation form

Note: If this button does not say 'Save & Go To Next Form' use the arrow button to select that option

Entering entry form data

Entry form



About your Hospital

1. Country
* must provide value

Pakistan
 Nigeria
 United Kingdom

2. Hospital name
* must provide value

About the patient

3. Date of admission to hospital
* must provide value

4. Sex
* must provide value

Male
 Female

5. Age
(Approximate if unknown)
* must provide value

0 characters remaining
years

WARNING! This patient is not eligible. Stop collecting data and leave the page without saving.

If you have started entering the data for an ineligible patient, do not collect any more data for this patient and leave the form without saving


Alerts will appear if any data entered deems the patient ineligible.

Randomising a patient

Once on the randomisation form, the randomisation number is provided.

You MUST record this in the medical records before proceeding to the treatment allocation

Randomisation form



CRASH-19

You have now randomised this patient to:

Randomisation number 53

Please record this number in the medical records (and on Q31 if using the paper CRF)
This is the only identifier used in the trial and is needed to trace the patient.

31. Randomisation number

Please confirm that the randomisation number has been recorded in the medical records?

* must provide value

Yes
 No

reset

You must have completed this before proceeding to the treatment allocation

Randomising a patient

1

To reveal the trial treatment click the 'Randomise' button below

32. Intervention(s) to be given

* must provide value

Randomize

Click randomise, then a pop up will appear confirming that you are about to randomise and the patient randomisation number

2

Randomizing Randomisation number "53"

Below you may perform randomization for Randomisation number "53" on the field **32. Intervention(s) to be given** (*treat*).

Randomize

Cancel

Click randomise again to reveal the allocated trial treatment on screen

3

Randomizing Randomisation number "53"



Randomisation number "53" was randomized for the field "**32. Intervention(s) to be given**" and assigned the value "Losartan 100mg" (2).

Close

Randomising a patient

35. Name of person randomising
(Full name)
* must provide value

Madeleine Cargill

35a. Email address of person randomising
* must provide value

madeleine.cargill92@gmail.com

Notes

Expand

Form Status

Save & Exit Form Save & Go To Next Form

-- Cancel --

Enter the name of the person randomising as it appears on the trial team members log.

You MUST 'Save & Exit' to save the randomisation - do not exit out of the form without saving

Randomising a patient

Upon saving the randomisation form, the person randomising will receive an email with the treatment allocation, dose and the automated date and time of randomisation

CRASH-19 Trial - Randomisation allocation for Patient '53' ↳ Inbox x

crash19@lshtm.ac.uk 3:47 PM (0 minutes ago)
to me ▾

Randomisation number: 53

Randomised by Madeleine Cargill (madeleine.cargill92@gmail.com)

This participant has been randomised to receive **Losartan 100mg.**

Randomised at **15:34** on the **22-06-2020**

PLEASE PRESCRIBE THE TREATMENT(S) AND ENSURE IT IS GIVEN ONCE DAILY UP TO 28 DAYS.

THE TREATMENT GIVEN MUST ALSO BE RECORDED IN THE MEDICAL RECORDS

Thank you,

CRASH-19 Trial

Clinical Trials Unit, LSHTM | Keppel Street, London WC1E 7HT

Tel [+44\(0\)20 7299 4684](tel:+44(0)2072994684) | Fax [+44\(0\)20 7299 4663](tel:+44(0)2072994663)

CRASH19@LSHTM.ac.uk

Viewing randomised patients at your site on the Record Status Dashboard

REDCap®
Logged in as madeleine.cargill92@gmail.com
Log out
REDCap Messenger

Project Home and Design

- Project Home
- Project status: Development

Data Collection

- Record Status Dashboard**
- View data collection status of all records
- Add / Edit Records
- View or edit existing records
- Show data collection instruments

Applications

On the navigation panel, click this to see all patients at your site

CRASH-19 CLINICAL TRIALS UNIT LONDON SCHOOL of HYGIENE & TROPICAL MEDICINE

CRASH-19 Development Mode

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Record Status Dashboard (all records)

Displayed below is a table listing all patients randomised at your associated site, and CRFs for each patient. To add a new participant, click the '+ Add new record' button. To view any existing patient CRFs, click the coloured **circle button** under the column for the CRF. To view the patient's record page, and all CRFs for that patient, click on the patient randomisation number. Different lists of patients can be viewed using the drop-down menu next to 'Dashboard displayed:'.
Note: Ensure the [Default dashboard] is selected to display the full list of patients and CRFs.

Dashboard displayed: [Default dashboard] v
Displaying record Page 1 of 1: "1" through "33" v of 30 records ALL (30) v records per page

+ Add new record

Displaying: Instrument status only | Lock status only | All status types

| Randomisation number | Consent | Entry | Randomisation | Outcome | Serious Adverse Reaction | Query |
|----------------------|---------|-------|---------------|---------|--------------------------|-------|
| 1 | ✓ + | ⊘ | ● | ● | ● + | ⊘ + |
| 2 | ⊘ + | ● | ● | ● | ● + | ● + |
| 3 | ● + | ● | ● | ● | ⊘ | ⊘ + |
| 4 | ● + | ● | ● | ● | ⊘ | ⊘ + |

Table of patients and their CRFs

Viewing patients data

The table of patient's on the Record Status Dashboard will show:




Click the patient randomisation number to access their record home page

| Patients | | CRFs for that patient | | | | |
|-----------------------|------------------------------------|----------------------------------|----------------------------------|----------------------------------|------------------------------------|------------------------------------|
| Randomisation number | Consent | Entry | Randomisation | Outcome | Serious Adverse Reaction | Query |
| 27-25 | <input checked="" type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> + | <input type="radio"/> |
| 27-26 | <input checked="" type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 28-11 | <input checked="" type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> + |
| 28-12 | <input checked="" type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> + | <input checked="" type="radio"/> + |
| 28-14 | <input checked="" type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> + | <input checked="" type="radio"/> + |
| 28-15 | <input checked="" type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 28-16 | <input checked="" type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> + | <input type="radio"/> |
| 33-1 | <input type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> + | <input type="radio"/> |
| 33-2 | <input type="radio"/> + | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> | <input checked="" type="radio"/> + | <input type="radio"/> |

A coloured radio button means there is saved data for this CRF

Uncoloured radio button means no data has been saved for that CRF

Adding outcome data







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| Data Collection Instrument | Form Status. Click on the radio buttons below to view/ add a form |
|--|--|
| Consent Complete this form first --> | <input checked="" type="radio"/> +  |
| Entry | <input checked="" type="radio"/>  |
| Randomisation | <input checked="" type="radio"/>  |
| Outcome | <input type="radio"/>  |
| Serious Adverse Reaction | <input type="radio"/> |
| Query | <input type="radio"/> |

Click on a patients randomisation number to go to the patient's 'record home page'.

This will display all CRFs associated to that patient, and whether they have been completed or not

To add a patients outcome form, click the grey radio button

Adding outcome data

5. Trial treatment given

Where the patient did not receive the allocated treatment or why the trial treatment was not given daily, please use the notes box to explain why.

5. Trial treatment given

Please tick all treatments that were allocated to this patient during randomisation

- Standard care
- Aspirin 150 mg
- Losartan 100 mg
- Losartan < 100 mg
- Simvastatin 80 mg

5a i. Aspirin 150mg - Total number of days

Record the number of days the full dose was given

0

1 characters remaining

Expand

6. Complications

Note, a text box is provided in the 'Trial treatment given' section.

Use this to explain any reason why the treatment(s) were not given as per protocol.

Adding outcome data

Expand

6. Complications

Before answering 'YES' to any questions in this section, please ensure that the event fulfils the definition given.

6a. Myocardial infarction Yes No reset

Detection of rise and/or fall of cardiac biomarker values (preferably troponin) with at least one value above the 99th percentile of the upper reference limit and with at least one of the following:

- 1. Symptoms of ischaemia*
- 2. ECG abnormalities: new or presumably new significant ST-T changes or new LBBB (left bundle branch block) or pathological Q waves*
- 3. Imaging evidence of new loss of viable myocardium, or new regional wall motion abnormality*
- 4. Identification of an intracoronary thrombus by angiography or autopsy*
- 5. Cardiac death with symptoms suggestive of myocardial ischaemia*
- 6. Stent thrombosis associated with MI when detected by coronary angiography or autopsy in the setting of myocardial ischaemia and with a rise and/or fall of cardiac biomarker values with at least one value above the 99th percentile URL*

6b. Congestive cardiac failure Yes No reset

A clinical diagnosis of heart failure may include the following symptoms: unusual breathlessness on light exertion, recurrent breathlessness when lying flat, fluid retention; jugular venous distension, pulmonary oedema on physical exam or chest x-ray presumed due to cardiac dysfunction.

6c. Severe cardiac arrhythmia Yes No reset

Any arrhythmia that causes symptoms.


6d. Myocarditis Yes

If you are reporting that the patient experienced any complications listed on the outcome form, please ensure that the trial's definition of that complication is met.

The definitions are provided with each complication

Adding outcome data

Outcome form

 **CRASH-19**

PLEASE COMPLETE AT DEATH, DISCHARGE OR DAY 28 WHICHEVER COMES FIRST

1.a. Hospital Name _____
1.b. Country Pakistan
2. Patient randomisation number 53
3. Outcome

3.0 Outcome Death Patient
* must provide value

4. Management
Only report management that occurred/was given after randomisation

4a. Admitted to ICU Yes No Needed
* must provide value

This is defined as 'a new focal neurological deficit with signs and symptoms lasting more than 24 hours'
* must provide value
 Yes No reset

6j. Gastrointestinal bleeding
Any significant upper or lower GI bleeding. The diagnosis of significant bleeding is clinical but may include patients with hypotension, tachycardia, or those likely to need transfusion, urgent endoscopy or surgery.
* must provide value
 Yes No reset

7. Person completing form

7a. Name * must provide value

7b. Job title * must provide value

7d. Date * must provide value D-M-Y

IF PATIENT DOES NOT HAVE ANY SERIOUS ADVERSE REACTIONS TO REPORT, PLEASE 'Save & Exit Form'

Notes

Form Status

Expand

Complete ALL fields on the outcome form and 'Save & Exit'

The logo for CRASH-19 is a stylized, pink, multi-lobed shape resembling a flower or a cluster of interconnected loops, with a white cross in the center.

CRASH-19

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