

# RECOVERY Respiratory Support: Respiratory Strategies in patients with coronavirus COVID-19 – CPAP, high-flow nasal oxygen, and standard care

<b>Submission date</b> 02/04/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/01/2022	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Current plain English summary as of 04/05/2021:

Background and study aims:

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged at the end of 2019 as a novel coronavirus. It has been declared as a global pandemic. Some people develop no symptoms, whilst others develop worsening breathing problems and may die. Throughout the world, a huge burden has been placed on intensive care units due to the number of people with worsening breathing problems that need to be placed on a ventilator (breathing machine). It is essential that we avoid ventilator use wherever possible to allow as many individuals as possible to benefit.

In this trial, we will test whether two treatments are better than standard treatment at preventing people from dying or needing to go on a ventilator.

Who can participate?

Adult hospital inpatients with suspected or proven COVID-19

What does the study involve?

Individuals that have or are believed to have COVID-19 that are requiring a certain amount of oxygen will be randomly allocated to receive one of three interventions. In the first group, participants will be placed on a tight-fitting mask (CPAP). In the second group, participants will receive oxygen blown quickly up their nose by a machine (HFNO). In the third arm, participants will receive standard treatment (a normal oxygen mask). Both CPAP and HFNO are already used routinely in the NHS for other conditions.

Where possible, we will seek informed consent from participants prior to trial enrolment. In some cases, the urgency of treatment may require that participants are enrolled and their

consent sought later. This is because some participants are likely to be confused and, due to COVID-19, visiting is restricted. In addition, for treatments to be effective, they will need to be started as quickly as possible to have the best possible outcomes.

We will record the need for people to be placed on a ventilator and death over a 30-day period. We will also see how long people spend on intensive care units and in hospital.

What are the possible benefits and risks of participating?

The planned interventions are already in routine use across NHS Hospitals. The interventions (HFNO and CPAP) may help to reduce the need for patients to go on a ventilator. However, they have some side-effects such as nausea, dryness to the mouth and nose, and pressure sores to the face.

Where is the study run from?

The trial is led by the University of Warwick Clinical Trials Unit

When is the study starting and how long is it expected to run for?

From March 2020 to June 2021

Who is funding the study?

The National Institute for Health Research (UK)

Who is the main contact?

Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn't ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

Previous plain English summary:

Background and study aims:

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged at the end of 2019 as a novel coronavirus. It has been declared as a global pandemic. Some people develop no symptoms, whilst others develop worsening breathing problems and may die. Throughout the world, a huge burden has been placed on intensive care units due to the number of people with worsening breathing problems that need to be placed on a ventilator (breathing machine). It is essential that we avoid ventilator use wherever possible to allow as many individuals as possible to benefit.

In this trial, we will test whether two treatments are better than standard treatment at preventing people from dying or needing to go on a ventilator.

Who can participate?

Adult patients with suspected or proven COVID-19 admitted to hospital

What does the study involve?

Individuals that have or are believed to have COVID-19 that are requiring a certain amount of oxygen will be randomly allocated to receive one of three interventions. In the first group, participants will be placed on a tight-fitting mask (CPAP). In the second group, participants will receive oxygen blown quickly up their nose by a machine (HFNO). In the third arm, participants will receive standard treatment (a normal oxygen mask). Both CPAP and HFNO are already used routinely in the NHS for other conditions.

Due to the urgency of treatment, we plan to enrol potential participants immediately and seek their consent later. This is because many participants are likely to be confused and due to COVID-19 visiting will be restricted. In addition, for the treatments to be effective, they will need to be started as quickly as possible to have the best outcomes.

We will record the need for people to be placed on a ventilator and death over a 30-day period. We will also see how long people spend on intensive care units and in hospital.

What are the possible benefits and risks of participating?

The planned interventions are already in routine use across NHS Hospitals. The interventions (HFNO and CPAP) may help to reduce the need for patients to go on a ventilator. However, they have some side-effects such as nausea, dryness to the mouth and nose, and pressure sores to the face.

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The trial is led by the University of Warwick Clinical Trials Unit

When is the study starting and how long is it expected to run for?

From March 2020 to May 2021

Who is funding the study?

The National Institute for Health Research (UK)

Who is the main contact?

Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn't ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

## Contact information

### Type(s)

Public

### Contact name

Dr Keith Couper

### ORCID ID

<https://orcid.org/0000-0003-2123-2022>

### Contact details

Clinical Trials Unit  
Warwick Medical School  
University of Warwick  
Coventry  
United Kingdom  
CV4 7AL  
+442476151179  
[k.couper@warwick.ac.uk](mailto:k.couper@warwick.ac.uk)

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

282338

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

Sponsor: 26/19-20, IRAS 282338

# Study information

## Scientific Title

In adult patients with known or suspected COVID-19, does the use of Continuous Positive Airway Pressure (CPAP) or high-flow nasal oxygen (HFNO), compared with standard care reduce mortality or need for tracheal intubation?

## Acronym

Recovery-RS

## Study objectives

CPAP is superior to standard care in reducing mortality or need for tracheal intubation in COVID-19 patients

HFNO is superior to standard care in reducing mortality or need for tracheal intubation in COVID-19 patients

CPAP is superior to HFNO in reducing mortality or need for tracheal intubation in COVID-19 patients

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 03/04/2020, the London - Brighton & Sussex Research Ethics Committee (Health Research Authority, Ground Floor, Skipton House, 80 London Road, London SE1 6LH; +44 0207 104 8241; [brightonandsussex.rec@hra.nhs.uk](mailto:brightonandsussex.rec@hra.nhs.uk)), ref: 20/HRA/1696

## Study design

Adaptive (group-sequential), pragmatic, randomised controlled, open-label, multi-centre, effectiveness trial

## Primary study design

Interventional

## Study type(s)

Treatment

## **Health condition(s) or problem(s) studied**

Respiratory failure in patients with known or suspected COVID-19 (SARS-CoV-2 infection)

## **Interventions**

Patients will be randomised in a 1:1:1 ratio to:

Arm 1: Continuous positive airway pressure (CPAP), administered according to local protocol /guidelines. Administration will be left to clinical discretion.

Arm 2: High flow nasal oxygen (HFNO) will be administered according to local protocol /guidelines. Administration will be left to clinical discretion.

Arm 3: Standard care. Standard oxygen therapy according to local protocol/guidelines.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Composite outcome comprising tracheal intubation or mortality within 30 days. Mortality will be reported from hospital records up until discharge and tracked after discharge. Intubation will be obtained from hospital data.

## **Key secondary outcome(s)**

Current secondary outcome measures as of 04/05/2021:

All outcome measures are assessed at up to 30-days or hospital discharge, whichever is later, and obtained from hospital records unless otherwise specified.

1. Intubation rate
2. Time to intubation
3. Time to death (mortality), obtained from hospital record or other source
4. Mortality in critical care (level 2/3)
5. Mortality during hospital stay
6. Mortality at 30 days, obtained from hospital record or other source
7. Length of stay in critical care (level 2/3)
8. Length of stay in hospital
9. Duration of invasive ventilation
10. Admission to ICU

Previous secondary outcome measures:

All outcome measures are assessed at up to 30-days or hospital discharge, whichever is later, and obtained from hospital records unless otherwise specified.

1. Intubation rate
2. Time to intubation
3. Time to death (mortality), obtained from hospital record or other source
4. Mortality in critical care (level 2/3)
5. Mortality during hospital stay
6. Mortality at 30 days, obtained from hospital record or other source
7. Length of stay in critical care (level 2/3)
8. Length of stay in hospital

## **Completion date**

02/06/2021

## **Eligibility**

## **Key inclusion criteria**

Current participant inclusion criteria as of 04/05/2021:

1. Adults  $\geq 18$  years
2. Hospital inpatient with suspected or proven COVID-19
3.  $\text{FiO}_2 \geq 0.4$  and  $\text{SpO}_2 \leq 94\%$
4. Plan for escalation to intubation if needed

Previous participant inclusion criteria:

1. Adults  $\geq 18$  years
2. Admitted to hospital with suspected or proven COVID-19
3. On 40% oxygen (or greater) with  $\text{SpO}_2 < 94\%$
4. Plan for escalation to intubation if needed

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Lower age limit**

18 years

## **Sex**

All

## **Key exclusion criteria**

Current participant exclusion criteria as of 04/05/2021:

1. Planned intubation and mechanical ventilation imminent within 1 hour
2. Known or clinically apparent pregnancy
3. Any absolute contraindication to CPAP or HFNO
4. Decision not to intubate due to ceiling of treatment or withdrawal of treatment anticipated
5. Equipment for both CPAP and HFNO not available

Previous participant exclusion criteria:

1. Planned intubation and mechanical ventilation imminent within 1 hour
2. Known or clinically apparent pregnancy
3. Any absolute contraindication to CPAP or HFNO
4. Decision not to intubate due to ceiling of treatment or withdrawal of care anticipated
5. Equipment for both CPAP and HFNO not available

## **Date of first enrolment**

06/04/2020

## **Date of final enrolment**

03/05/2021

## **Locations**

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre****Warwick Clinical Trials Unit**

Warwick Medical School

University of Warwick

Coventry

United Kingdom

CV4 7AL

**Study participating centre****Aintree Hospital**

Lower Lane

Liverpool

United Kingdom

L9 7AL

**Study participating centre****Altnagelvin Hospital**

Glenshane Road

Londonderry

United Kingdom

BT47 6SB

**Study participating centre****Barnet Hospital**

Wellhouse Lane

Barnet

United Kingdom

EN5 3DJ

**Study participating centre**

**Bedford Hospital**

Kempston Road  
Bedford  
United Kingdom  
MK42 9DJ

**Study participating centre****Belfast City Hospital**

51 Lisburn Road  
Belfast  
United Kingdom  
BT9 7AB

**Study participating centre****Castle Hill Hospital**

Castle Road  
Cottingham  
United Kingdom  
HU16 5JQ

**Study participating centre****Charing Cross Hospital (Lead Centre)**

Fulham Palace Road  
London  
United Kingdom  
W6 8RF

**Study participating centre****Colchester General Hospital**

Turner Road  
Colchester  
United Kingdom  
CO4 5JL

**Study participating centre****Conquest Hospital, Hastings**

The Ridge  
St. Leonards-On-Sea  
United Kingdom  
TN37 7RD



**Study participating centre**  
**Croydon University Hospital**  
London Road  
Croydon  
United Kingdom  
CR7 7YE

**Study participating centre**  
**Derriford Hospital**  
Derriford Road  
Crownhill  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**Diana, Princess Of Wales Hospital**  
Scartho Road  
Grimsby  
United Kingdom  
DN33 2BA

**Study participating centre**  
**Eastbourne District General**  
Kings Drive  
Eastbourne  
United Kingdom  
BN21 2UD

**Study participating centre**  
**Fairfield General Hospital**  
Rochdale Old Road  
Bury  
United Kingdom  
BL9 7TD

**Study participating centre**  
**Freeman Hospital**  
Freeman Road

High Heaton  
Newcastle Upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Glenfield Hospital**  
Groby Road  
Leicester  
United Kingdom  
LE3 9QP

**Study participating centre**  
**Good Hope Hospital**  
Rectory Road  
Sutton Coldfield  
United Kingdom  
B75 7RR

**Study participating centre**  
**Harefield Hospital**  
Hill End Road  
Harefield  
United Kingdom  
UB9 6JH

**Study participating centre**  
**Heartlands Hospital**  
Bordesley Green East  
Birmingham  
United Kingdom  
B9 5SS

**Study participating centre**  
**Hull Royal Infirmary**  
Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**  
**Inverclyde Royal Hospital**  
Larkfield Road  
Greenock  
United Kingdom  
PA16 0XN

**Study participating centre**  
**Ipswich Hospital**  
Heath Road  
Ipswich  
United Kingdom  
IP4 5PD

**Study participating centre**  
**James Paget University Hospital**  
Lowestoft Road  
Gorleston  
Great Yarmouth  
United Kingdom  
NR31 6LA

**Study participating centre**  
**Jersey General Hospital**  
The Parade  
Jersey  
United Kingdom  
JE1 3UH

**Study participating centre**  
**Kent & Canterbury**  
Ethelbert Road  
Canterbury  
United Kingdom  
CT1 3NG

**Study participating centre**  
**King's College (Denmark Hill)**  
Denmark Hill  
London

United Kingdom  
SE5 9RS

**Study participating centre**

**Leighton Hospital**

Leighton

Crewe

United Kingdom

CW1 4QJ

**Study participating centre**

**Lister Hospital**

Coreys Mill Lane

Stevenage

United Kingdom

SG1 4AB

**Study participating centre**

**Macclesfield District General Hospital**

Victoria Road

Macclesfield

United Kingdom

SK10 3BL

**Study participating centre**

**Manor Hospital**

Moat Road

Walsall

United Kingdom

WS2 9PS

**Study participating centre**

**Medway Maritime Hospital**

Windmill Road

Gillingham

United Kingdom

ME7 5NY

**Study participating centre**

**Musgrove Park Hospital**

Musgrove Park  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre****New Cross Hospital**

Wolverhampton Road  
Heath Town  
Wolverhampton  
United Kingdom  
WV10 0QP

**Study participating centre****Norfolk And Norwich University Hospital**

Colney Lane  
Colney  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre****North Manchester**

Delaunays Road  
Manchester  
United Kingdom  
M8 5RB

**Study participating centre****Nottingham City Hospital**

Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre****Princess Of Wales Hospital (Wales)**

Coity Road

Bridgend  
United Kingdom  
CF31 1RQ

**Study participating centre**  
**Princess Royal Hospital, Telford**  
Apley Castle  
Grainger Drive  
Telford  
United Kingdom  
TF1 6TF

**Study participating centre**  
**Princess Royal University Hospital**  
Farnborough Common  
Orpington  
United Kingdom  
BR6 8ND

**Study participating centre**  
**Queen Alexandra Hospital**  
Southwick Hill Road  
Cosham  
Portsmouth  
United Kingdom  
PO6 3LY

**Study participating centre**  
**Queen Elizabeth Hospital – Gateshead**  
Sheriff Hill  
Gateshead  
United Kingdom  
NE9 6SX

**Study participating centre**  
**Queen Elizabeth Hospital (Birmingham)**  
Queen Elizabeth Medical Centre  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TH

**Study participating centre**  
**Queen Elizabeth University Hospital, Glasgow**  
1345 Govan Road  
Glasgow  
United Kingdom  
G51 4TF

**Study participating centre**  
**Queens Medical Centre**  
Nottingham University Hospital  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**  
**Raigmore Hospital**  
Old Perth Rd  
Inverness  
United Kingdom  
IV2 3UJ

**Study participating centre**  
**Royal Alexandra Hospital, Paisley**  
Corsebar Road  
Paisley  
United Kingdom  
PA2 9PN

**Study participating centre**  
**Royal Brompton**  
Sydney Street  
London  
United Kingdom  
SW3 6NP

**Study participating centre**

**Royal Gwent Hospital**

Cardiff Road  
Newport  
Gwent  
United Kingdom  
NP20 2UB

**Study participating centre****Royal Liverpool University Hospital**

Prescot Street  
Liverpool  
United Kingdom  
L7 8XP

**Study participating centre****Royal Marsden (London)**

Fulham Road  
London  
United Kingdom  
SW3 6JJ

**Study participating centre****Royal Marsden (Surrey)**

Downs Road  
Sutton  
United Kingdom  
SM2 5PT

**Study participating centre****Royal Oldham Hospital**

Rochdale Road  
Oldham  
United Kingdom  
OL1 2JH

**Study participating centre****Russell's Hall**

Pensnett Road  
Dudley  
United Kingdom  
DY1 2HQ



**Study participating centre**

**Salford Royal Hospital**

Stott Lane  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**

**Scunthorpe General Hospital**

Cliff Gardens  
Scunthorpe  
United Kingdom  
DN15 7BH

**Study participating centre**

**South Tyneside District Hospital**

Harton Ln  
South Shields  
United Kingdom  
NE34 0PL

**Study participating centre**

**Southmead Hospital**

Southmead Road  
Westbury-On-Trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**

**St George's Hospital**

Blackshaw Road  
London  
United Kingdom  
SW17 0QT

**Study participating centre**

**St Mary's Hospital**  
Praed Street  
London  
United Kingdom  
W2 1NY

**Study participating centre**  
**St Thomas' Hospital**  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**  
**Stepping Hill Hospital**  
Poplar Grove  
Stockport  
United Kingdom  
SK2 7JE

**Study participating centre**  
**Sunderland Royal Hospital**  
Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**The Christie NHS Foundation Trust**  
550 Wilmslow Road  
Withington  
Manchester  
United Kingdom  
M20 4BX

**Study participating centre**  
**The Grange University Hospital**  
Caerleon Road  
Cwmbran  
United Kingdom  
NP44 8YN

**Study participating centre**  
**The Royal Victoria Infirmary**  
Queen Victoria Road  
Newcastle Upon Tyne  
United Kingdom  
NE1 4LP

**Study participating centre**  
**Torbay Hospital**  
Newton Road  
Torquay  
United Kingdom  
TQ2 7AA

**Study participating centre**  
**University Hospital Southampton**  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**  
**Victoria Hospital**  
Hayfield Road  
Kirkcaldy  
United Kingdom  
KY2 5AH

**Study participating centre**  
**Warwick Hospital**  
Lakin Road  
Warwick  
United Kingdom  
CV34 5BW

**Study participating centre**  
**Watford General Hospital**  
Vicarage Road

Watford  
United Kingdom  
WD18 0HB

**Study participating centre**

**West Suffolk Hospital**

Hardwick Lane  
Bury St. Edmunds  
United Kingdom  
IP33 2QZ

**Study participating centre**

**William Harvey Hospital, Ashford**

Kennington Road  
Willesborough  
Ashford  
United Kingdom  
TN24 0LZ

**Study participating centre**

**Wishaw General Hospital**

50 Netherton Street  
Wishaw  
United Kingdom  
ML2 0DP

**Study participating centre**

**Wrexham Maelor Hospital**

Croesnewydd Road  
Wrexham Technology Park  
Wrexham  
United Kingdom  
LL13 7TD

**Study participating centre**

**Wythenshawe Hospital**

Southmoor Road  
Wythenshawe  
Manchester  
United Kingdom  
M23 9LT

# Sponsor information

## Organisation

University of Warwick

## ROR

<https://ror.org/01a77tt86>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		24/01/2022	25/01/2022	Yes	No

<a href="#">Protocol article</a>	protocol	29/07/2020	03/08/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Preprint results</a>		04/08/2021	31/08/2021	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes