

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting
16th November 2020

Agenda

1. Introductions
2. Update on progress
3. REGN-COV2
4. Tocilizumab
5. Aspirin
6. Other developments
7. Trial procedures
8. Pregnancy update
9. Q&A

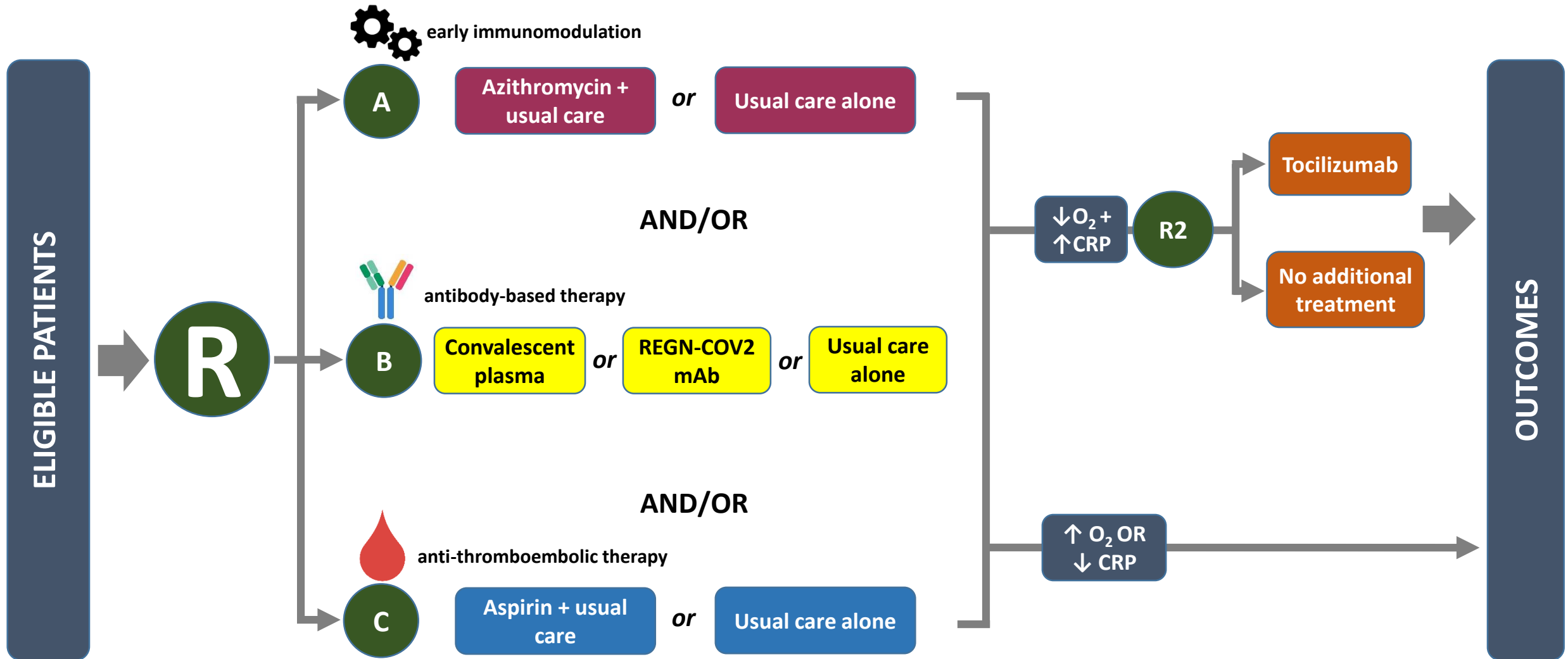
Introductions



- One of the central study team will talk to the agenda
- If you have questions please enter them into the “Q&A” on the right side of your screen.
- Questions may be answered directly or to the whole group

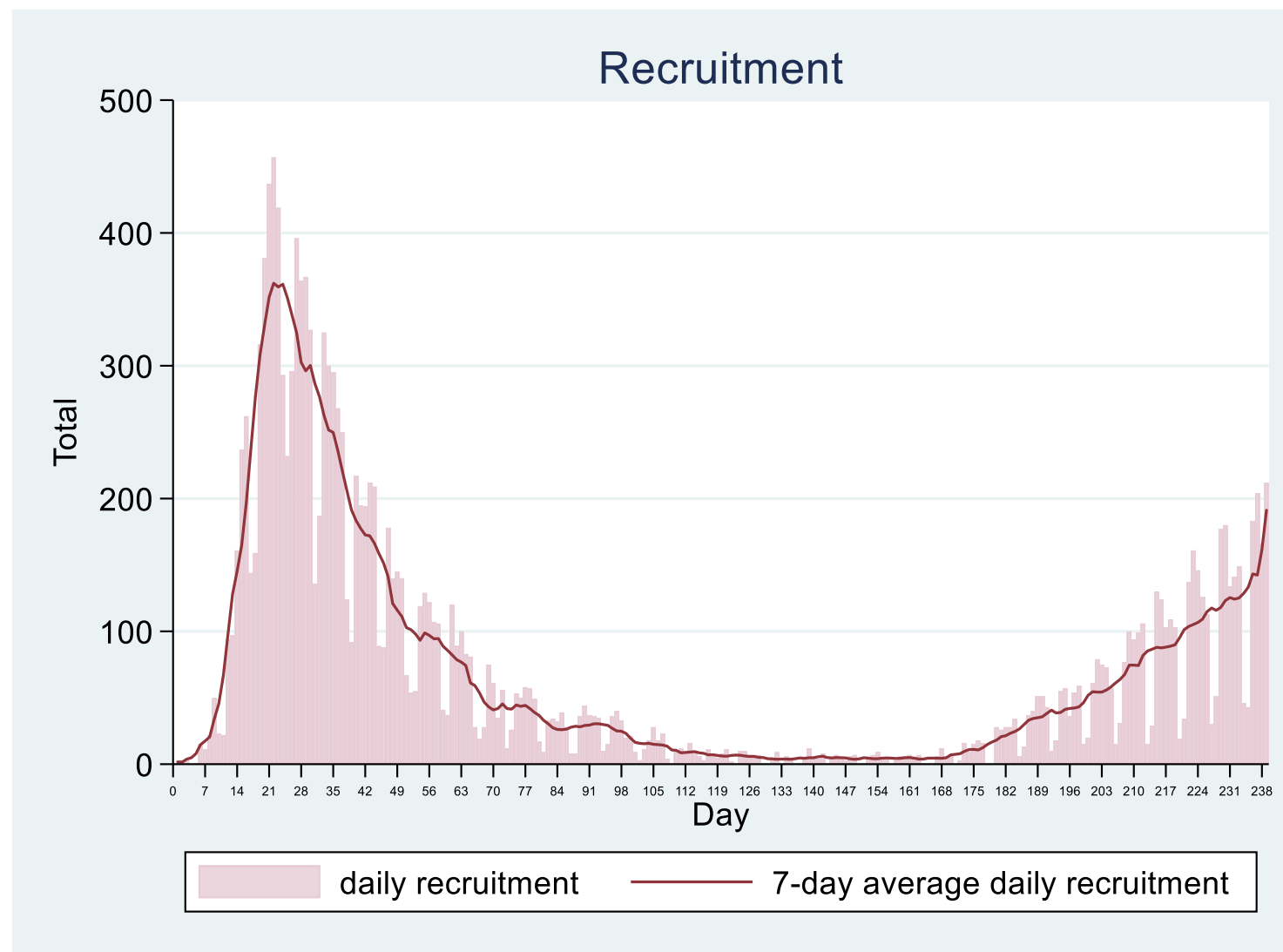
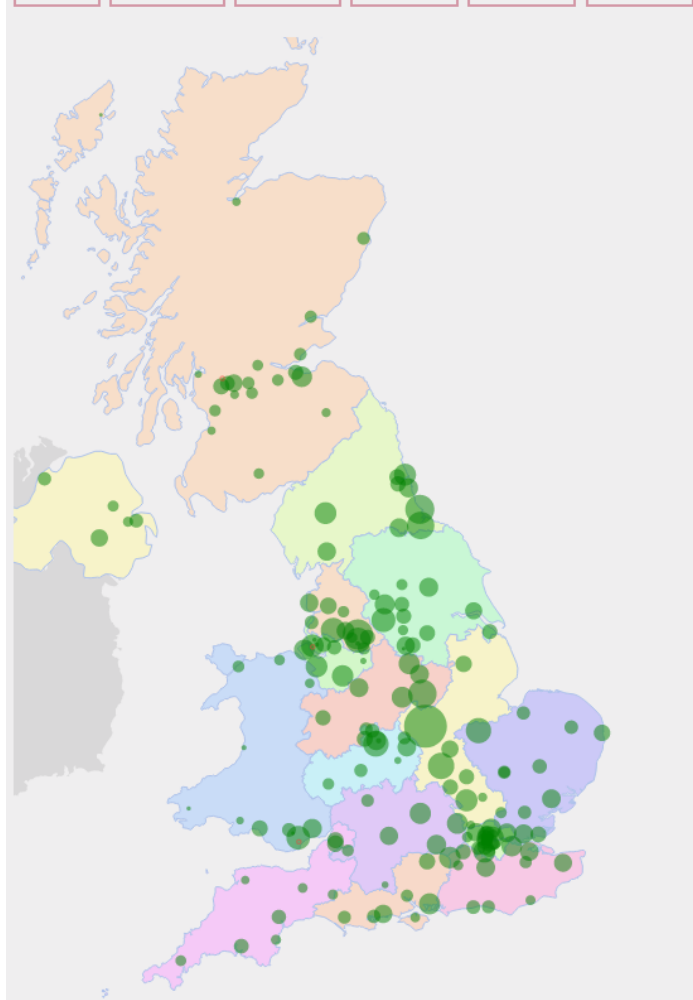
PROGRESS UPDATE

Design



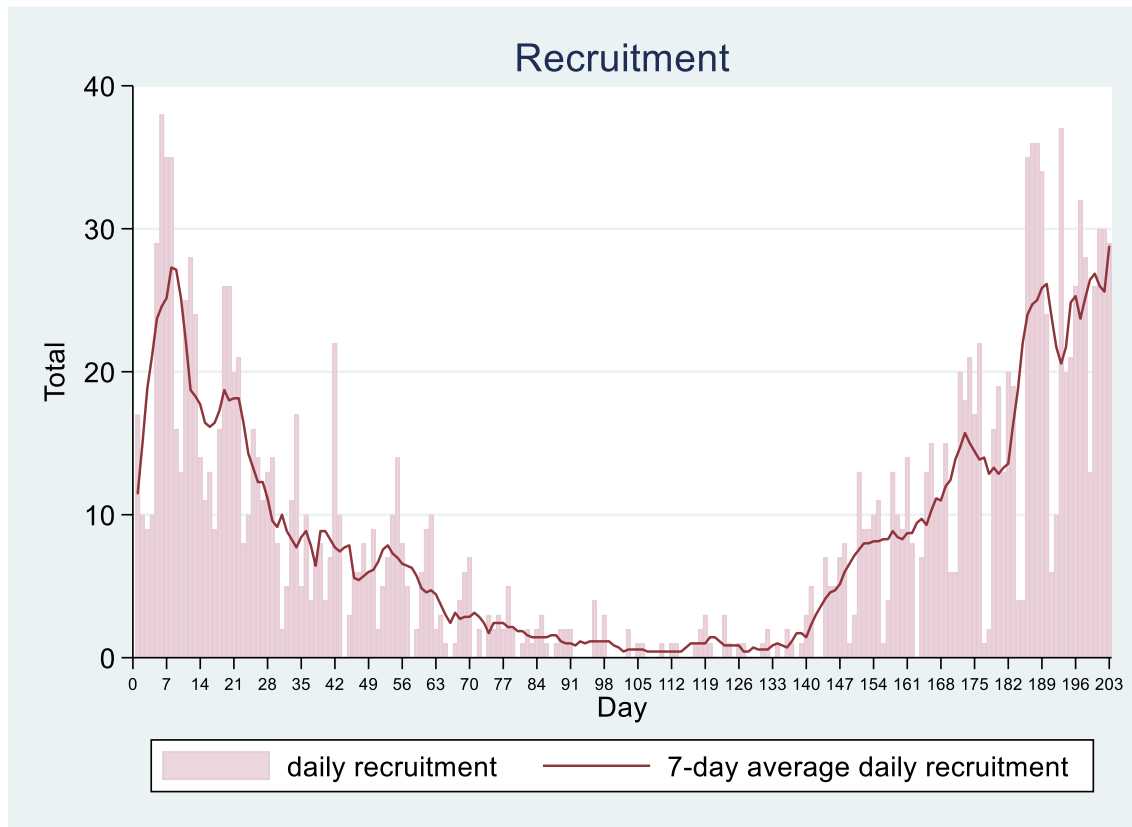
Recruitment by site and by time

Active Sites	Recruiting Sites	Participants	Phase 2 rands.	Phase 3 rands.	Phase 4 rands.
176	173	17209	1798	4397	422

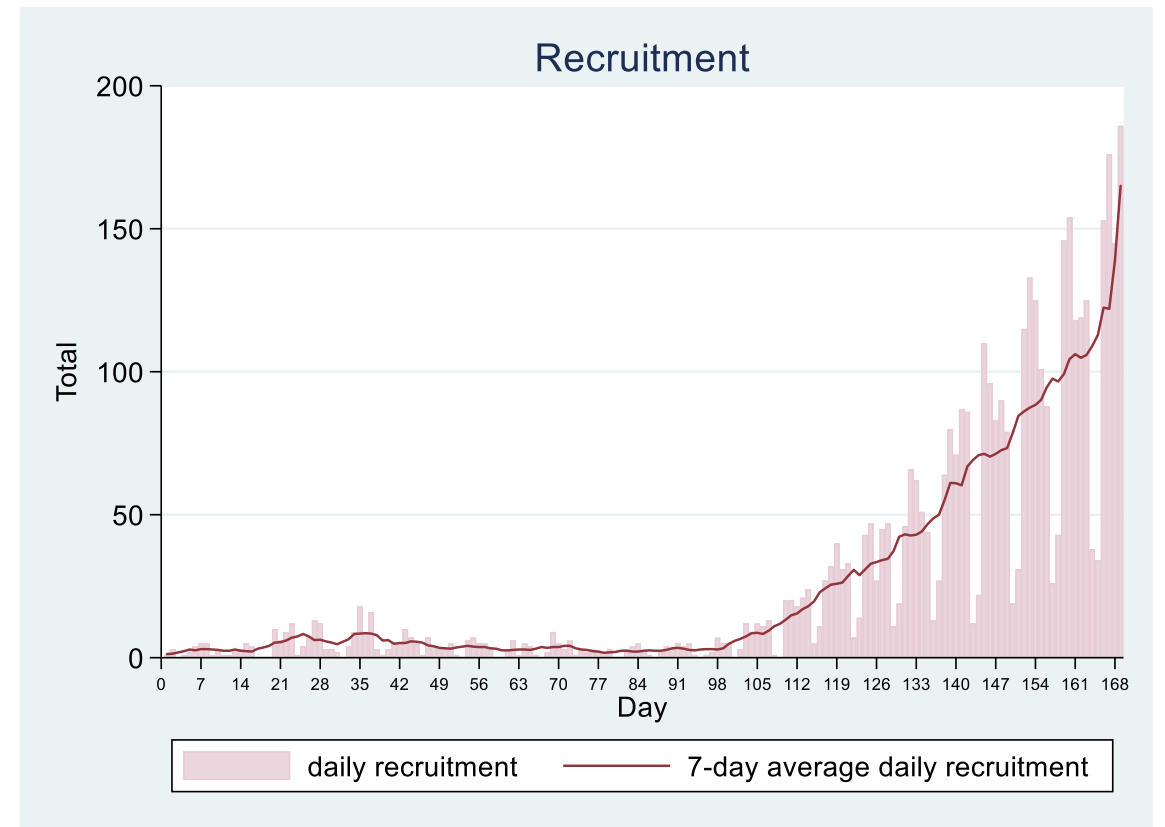


Recruitment

- Tocilizumab vs control



- Convalescent plasma vs REGN-COV2 vs control



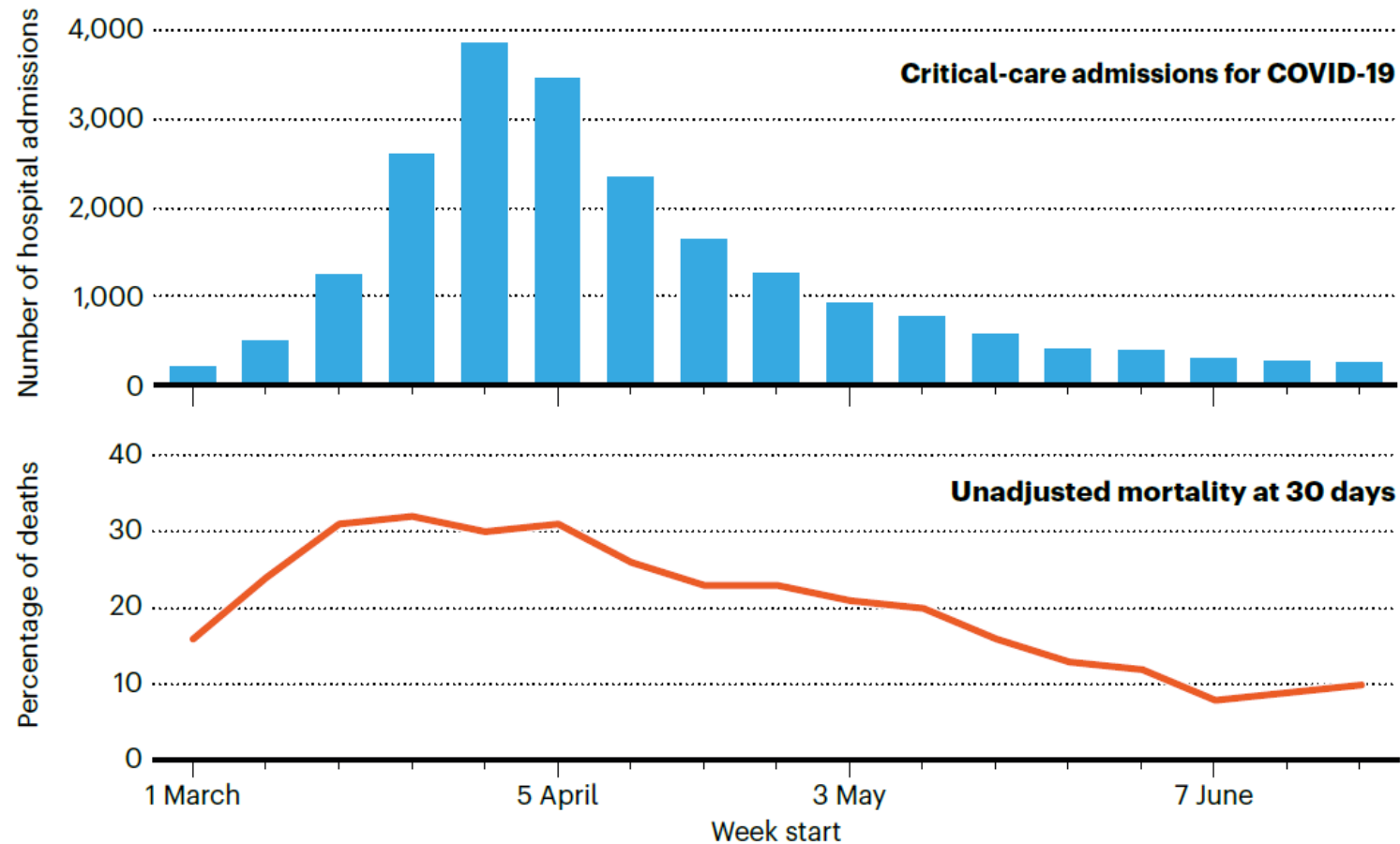
Recruitment



- As local outbreaks occur, please consider discussing with your teams how to ensure that all available admissions with Covid-19 are identified and enrolled if possible
 - Daily catch-up with admitting teams
 - Links with laboratory for all positive swabs among patients to be reported
- Average recruitment remains at about 12% of all COVID-19 admissions, but with significant variation between sites

How long until the next result?

- Determined by recruitment rate and death rate



Recruitment

- Pilot of additional funding for weekend working in November underway at 6 trusts in England
- RECOVERY now active on Associate PI scheme
 - Webinars on 13th & 17th November
 - Further details at:

<https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040>

NIHR | National Institute for Health Research

Associate Principal Investigator (PI) Scheme

The NIHR Associate Principal Investigator (PI) scheme aims to develop junior doctors, nurses and allied health professionals to become the PIs of the future at the same time as helping to deliver studies to time and target. Registration is quick and easy, just follow the steps below.

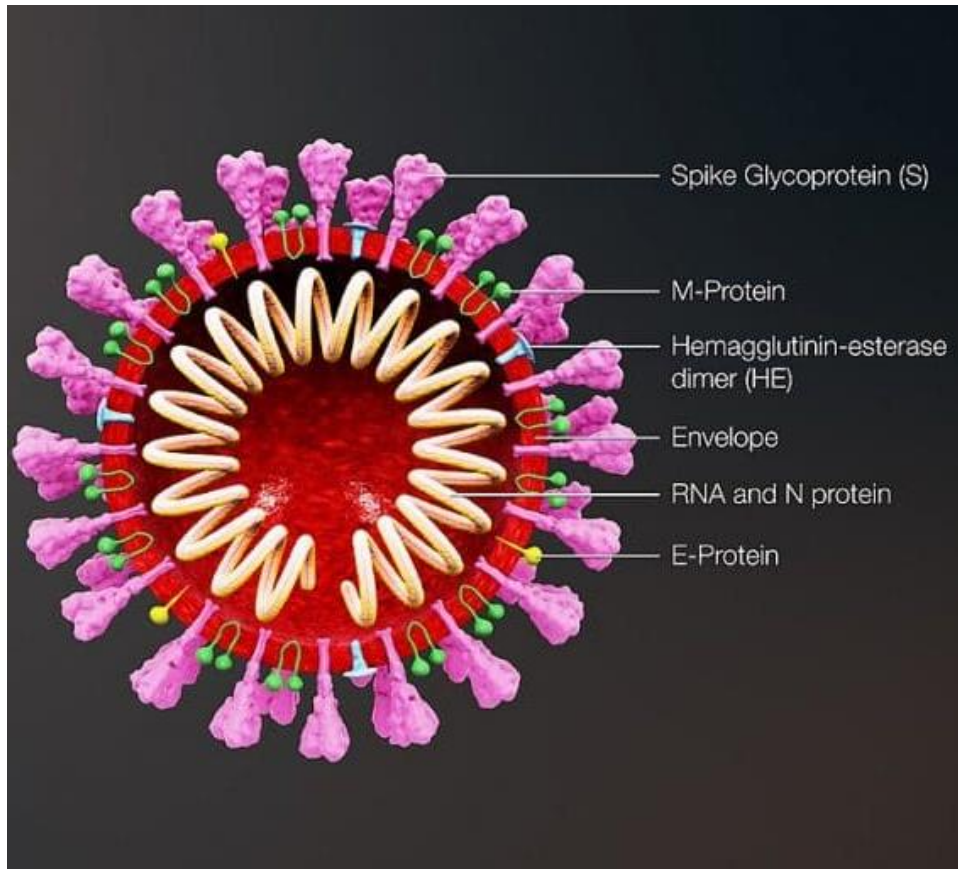
Register study	Check if the study you want to register to be Associate PI for is on the list of registered studies . If not then complete the Associate PI Scheme Study Registration Form .
Register yourself	Register to the scheme by completing the API Scheme Applicant Registration Form once you have approval from the Site PI and CTU Study / Trial Manager
Complete Checklist	Once you are registered to the scheme you will be sent a welcome email with a link to the Associate PI Scheme Checklist which you need to complete and get signed off by your PI and the CTU Study / Trial Manager within six months of registering to the scheme.
Receive certificate	Once you have submitted your fully signed off Checklist the NIHR Associate PI Scheme Team will issue you with a certificate. You are then free to register to another study at the same or another site.

For further information about the scheme, please visit the [NIHR Associate PI Scheme website](#).
If you have any questions about the scheme please email the NIHR Associate PI Scheme Team on associatepischeme@nihr.ac.uk.

REGN-COV2

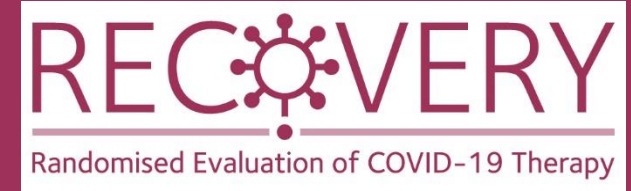
REGN-COV2

- REGN-COV2 is a mixture of two monoclonal antibodies (mAbs: REGN10933 and REGN10987)



- These are fully human antibodies directed against spike protein
- Two different antibodies mean that if virus mutates its spike protein such that one antibody doesn't bind so well, the other antibody probably still will

REGN-COV2 site setup



1. Local PIs need to complete online training and confirmation form
 - They should ask other staff involved at site to also do this, but not require before site activation
2. Pharmacy need to be ready to support new arm
 - Review Pharmacy Manual on website and complete local risk assessment to determine where mAb will be prepared
 - Confirm staff details to RECOVERY team
3. >100 sites now in set-up process (with ~80 actively recruiting); still waiting to hear from ~50

REGN-COV2 dos and don'ts

- Please **DO NOT** indicate REGN-COV2 is available if system suggests it is not *unless you are absolutely sure!*

Are the following treatments available?

A15.1 Azithromycin

☐

A15B.1 Convalescent plasma

☐

A15B.2 Synthetic monoclonal antibodies
(REGN10933+REGN10987)

☐ No

Please check with your PI before changing

- Please don't ignore the warning!

A15B.2 Synthetic monoclonal antibodies
(REGN10933+REGN10987)

Please check with your PI before changing

Please ensure this treatment is definitely available before continuing

Yes

- Otherwise the participant may be allocated a treatment they can't have ☹️

When to include REGN-COV2



- REGN-COV2 should be administered as soon after randomisation as possible
- If being prepared in pharmacy, this may not be until next working day
- If delay is likely to be longer (e.g. at weekend), please indicate that mAb is unavailable on randomisation form so it will not be allocated

TOCILIZUMAB

Tocilizumab

- 1800 randomised
- Sufficient tocilizumab supply for 4000 randomised, but all now at sites
- Please ensure you consider this randomisation for appropriate participants:
 - On oxygen (or sats <92%)
 - CRP ≥ 75 mg/L

- Increased risk of venous and arterial thrombosis observed in COVID-19, which may contribute to morbidity and mortality
- Platelets recognised as both activated by inflammation (making them more 'sticky') and also driving inflammation
- Aspirin 150 mg once daily recommended by CTAP antithrombotic subcommittee
- Added to protocol in V10.1 which went 'live' on 6th November 2020

Aspirin FAQs

Q Why 150 mg?

A Potential risk of underdosing larger patients with 75 mg and bleeding risk little different

Q Should we give a PPI with aspirin?

A Gastroprotection can be used at the discretion of the treating physician

Q What about other VTE prophylaxis?

A Other VTE prophylaxis (e.g. heparin) should not be modified by allocation to aspirin or control

OTHER DEVELOPMENTS

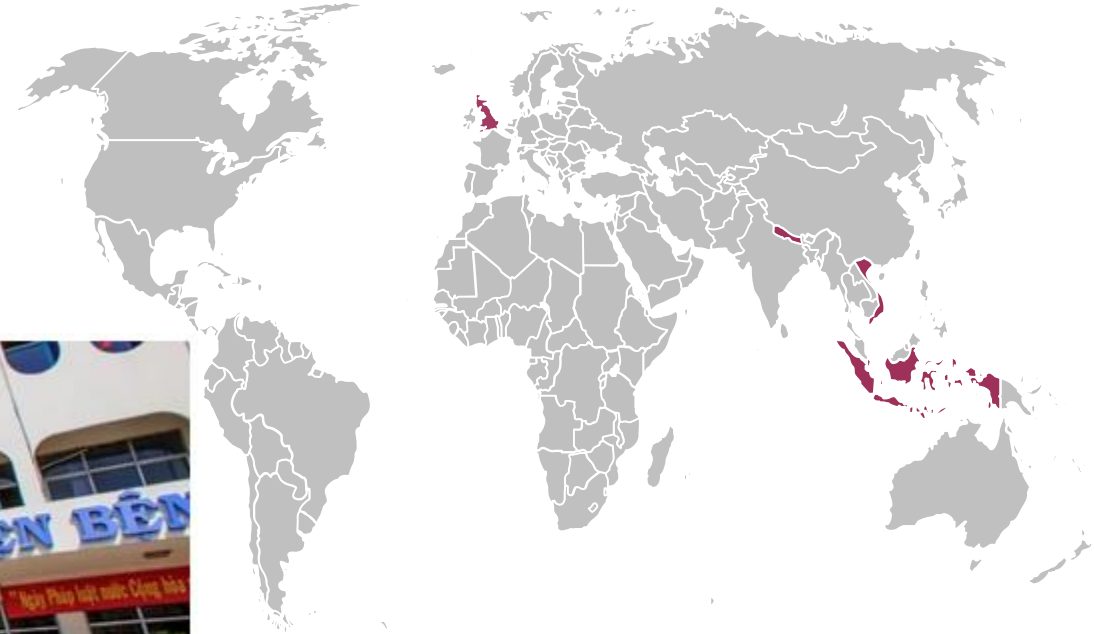
Other developments: RECOVERY international



- Funding agreed by Wellcome
- Discussions are progressing with Vietnam, Indonesia and Nepal



Oxford University Clinical Research Unit, Ho Chi Minh City, Vietnam



TRIAL PROCEDURES

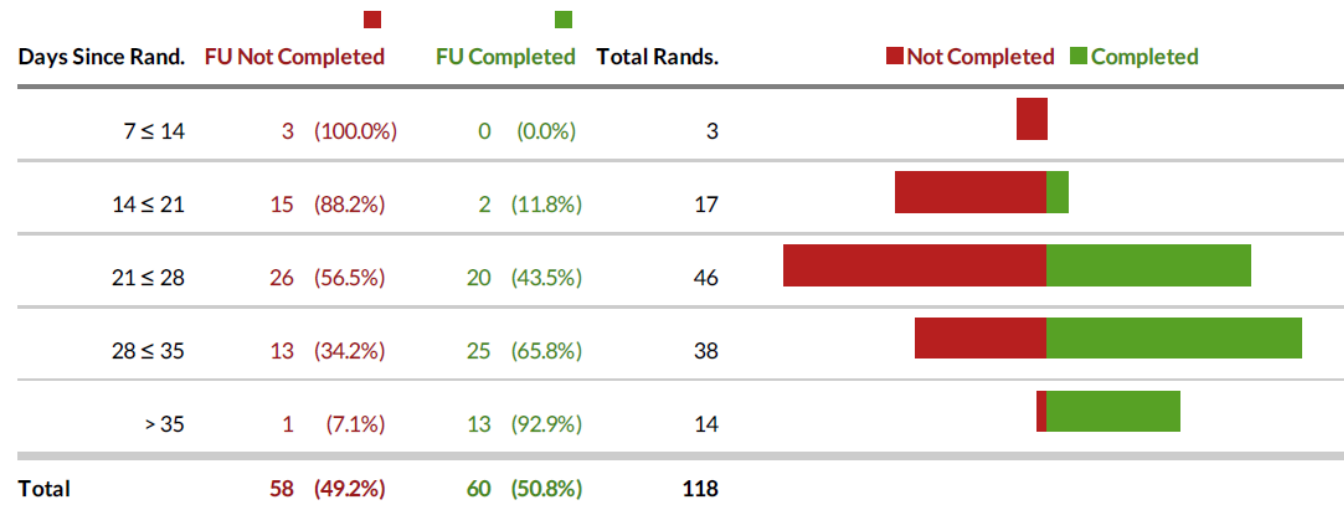
Serum samples

- **All** participants entering antibody comparison (CP vs mAb vs control) need to have serum sample collected prior to randomisation
- Can be taken with G&S sample after consent prior to randomisation to limit venepunctures
- Must be taken for all participants in that comparison (regardless of allocation)

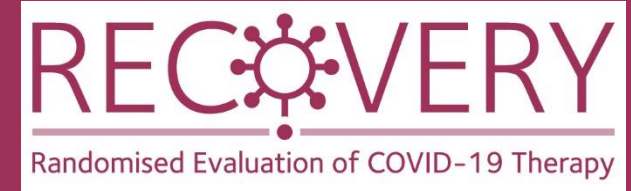
Completeness of follow-up

- Weekly reminders highlighting participants randomised >28 days ago without complete form **and also** those needing an Antibody Comparison 72h safety form
- Please do complete these as soon as possible

Follow-up form completion summary



Carry on recruiting!



- RECOVERY remains the largest global trial in COVID-19 and is an exemplar of what trials can do (both in and after pandemic)
- Current therapies are exciting, but need reliable data before they should be used routinely
- Thank you for your support!

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting for Pregnancy

16 November 2020

RECOVERY for pregnant women



1. Update on covid-19 and pregnancy
2. Update on adaptations
3. Update on UKOSS
4. Future plans
5. Q&A

Covid-19 and pregnancy

RESEARCH

OPEN ACCESS

Check for updates

Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study

Marian Knight,¹ Kathryn Bunch,¹ Nicola Vousden,² Edward Morris,³ Nigel Simpson,⁴ Chris Gale,⁵ Patrick O'Brien,⁶ Maria Quigley,¹ Peter Brocklehurst,⁷ Jennifer J Kurinczuk,¹ On behalf of the UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group

For numbered affiliations see end of the article.

Correspondence to: M Knight marian.knight@npeu.ox.ac.uk (or @MarianKnight and @NPEU_UKOSS on Twitter: ORCID 0000-0002-1984-4575) Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2020;369:m2107 <http://dx.doi.org/10.1136/bmj.m2107>

Accepted: 27 May 2020

ABSTRACT OBJECTIVES

To describe a national cohort of pregnant women admitted to hospital with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in the UK, identify factors associated with infection, and describe outcomes.

DESIGN

Prospective using the UK Obstetric Surveillance System

SETTING

All 194 obstetric units in the UK

over, and 145 (34%) had pre-existing comorbidities. 266 (62%) women gave birth or had a pregnancy loss; 196 (73%) gave birth at term. Forty one (10%) women admitted to hospital needed respiratory support, and five (1%) women died. Twelve (5%) of 265 infants tested positive for SARS-CoV-2 RNA, six of them within

BMJ: first published as 10.1136/bmj.m2107 on 1 September 2020

OPEN ACCESS

Check for updates

FAST TRACK

Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis

John Allotey,^{1,2} Elena Stallings,^{3,4} Mercedes Bonet,⁵ Magnus Yap,⁶ Shaunak Chatterjee,⁶ Tania Kew,⁶ Luke Debenham,⁶ Anna Clavé Llavall,⁶ Anushka Dixit,⁶ Dengyi Zhou,⁶ Rishab Balaji,⁶ Siang Ing Lee,¹ Xiu Qiu,^{7,8,9} Mingyang Yuan,^{1,7} Dyuti Coomaraswamy,¹ Madelon van Wely,¹⁰ Elizabeth van Leeuwen,¹¹ Elena Kostova,¹⁰ Heinke Kunst,^{12,13} Asma Khalil,¹⁴ Simon Tiberi,^{12,13} Vanessa Brizuela,⁵ Nathalie Broutet,⁵ Edna Kara,³ Caron Rahn Kim,⁵ Anna Thorson,⁵ Olufemi T Oladapo,⁵ Lynne Mofenson,¹⁵ Javier Zamora,^{3,4,16} Shakila Thangaratinam,^{2,17} for PregCOV-19 Living Systematic Review Consortium

For numbered affiliations see end of the article.

Correspondence to: S Thangaratinam s.thangaratinam.1@bham.ac.uk (or @thangaratinam on Twitter: ORCID 0000-0002-4254-460X) Additional material is published online only. To view please visit the journal online.

ABSTRACT OBJECTIVE

To determine the clinical manifestations, risk factors, and maternal and perinatal outcomes in pregnant and recently pregnant women with suspected or confirmed coronavirus disease 2019 (covid-19).

DESIGN

Living systematic review

DATA

Med

data

(CNK)

2019

soci.

meta-analysis was performed, with estimates pooled as odds ratios and proportions with 95% confidence intervals. All analyses will be updated regularly.

RESULTS

77 studies were included. Overall, 10% (95% confidence interval 7% to 14%; 28 studies, 11 432 women) of suspected and recently suspected women

BMJ: first published as 10.1136/bmj.m3320 on 1 September 2020

EDITORIALS

Include pregnant women in research—particularly covid-19 research

Adapting interventions and changing attitudes will drive scientific progress

Marian Knight,¹ R Katie Morris,² Jenny Furniss,³ Lucy C Chappell⁴

The UK Confidential Enquiries into Maternal Deaths have repeatedly highlighted inequities in the medical treatment of pregnant and postpartum women, noting that women are denied investigations and life preserving treatments simply because they are pregnant or breastfeeding.^{1,2} These inquiries emphasise that the default position should be to investigate and treat pregnant and breastfeeding women in the same way as non-pregnant women, unless there are clear reasons not to.¹

Clinical trials, particularly those of drug treatments, have typically automatically excluded pregnant or breastfeeding women—meaning data are unavailable or breastfeeding allows safety concerns to be allayed for women, their families, and healthcare professionals. Even if regulatory barriers have been overcome, gatekeeping or inertia may occur if local ethics committees take an overwhelming precautionary approach, overriding recognition of the potential benefits of including pregnant and breastfeeding women. This problem can be mitigated by a strong network of maternity researchers, familiar with delivering drug trials in pregnancy, who can be rapidly mobilised to help implement studies.

Clinical trials, particularly those of drug treatments, have typically automatically excluded pregnant or breastfeeding women—meaning data are unavailable

Maternal, Newborn and Infant Clinical Outcome Review Programme



Saving Lives, Improving Mothers' Care

Rapid report: Learning from SARS-CoV-2-related and associated maternal deaths in the UK

BMJ: first published as 10.1136/bmj.m3305 on 24 August 2020

CDC (US) data on pregnant women

Morbidity and Mortality Weekly Report

Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020

Laura D. Zambrano, PhD^{1,*}; Sascha Ellington, PhD^{1,*}; Penelope Strid, MPH¹; Romeo R. Galang, MD¹; Titilope Oduyebo, MD¹; Van T. Tong, MPH¹; Kate R. Woodworth, MD¹; John F. Nahabedian III, MS¹; Eduardo Azziz-Baumgartner, MD¹; Suzanne M. Gilboa, PhD¹; Dana Meaney-Delman, MD¹; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team

On November 2, 2020, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

Studies suggest that pregnant women might be at increased risk for severe illness associated with coronavirus disease 2019 (COVID-19) (1,2). This report provides updated information about symptomatic women of reproductive age (15–44 years) with laboratory-confirmed infection with SARS-CoV-2, the virus that causes COVID-19. During January 22–

Data on laboratory-confirmed and probable COVID-19 cases[†] were electronically reported to CDC using a standardized case report form[§] or NNDSS[¶] as part of COVID-19 surveillance efforts. Data are reported by health departments and can be updated by health departments as new information becomes available. This analysis included cases initially reported to CDC during January 22–October 3, 2020, with data updated as of October 28, 2020. Cases were limited to those in symp-

Summary

What is already known about this topic?

Limited information suggests that pregnant women with COVID-19 might be at increased risk for severe illness compared with nonpregnant women.

What is added by this report?

In an analysis of approximately 400,000 women aged 15–44 years with symptomatic COVID-19, intensive care unit admission, invasive ventilation, extracorporeal membrane oxygenation, and death were more likely in pregnant women than in nonpregnant women.

What are the implications for public health practice?

Pregnant women should be counseled about the risk for severe COVID-19–associated illness including death; measures to prevent infection with SARS-CoV-2 should be emphasized for pregnant women and their families. These findings can inform clinical practice, risk communication, and medical countermeasure allocation.

New National Restrictions from 5 November

9. Protecting people more at risk from coronavirus

If you are over 60 or clinically vulnerable, you could be at higher risk of severe illness from coronavirus. You:

- should be especially careful to follow the rules and minimise your contacts with others
- should continue to wash your hands carefully and more frequently than usual and maintain thorough cleaning of frequently touched areas in your home and/or workspace

Clinically vulnerable people are those who are:

- aged 70 or over (regardless of medical conditions)
- under 70 with an underlying health condition listed below (that is, anyone instructed to get a flu jab each year on medical grounds):
 - chronic (long-term) mild to moderate respiratory diseases, such as asthma, chronic obstructive pulmonary disease (COPD), emphysema or bronchitis
 - chronic heart disease, such as heart failure
 - chronic kidney disease
 - chronic liver disease, such as hepatitis
 - chronic neurological conditions, such as Parkinson's disease, motor neurone disease, multiple sclerosis (MS) or cerebral palsy
 - diabetes
 - problems with the spleen
 - a weakened immune system as the result of certain conditions or medicines they are taking (such as steroid tablets)
 - being seriously overweight (a body mass index (BMI) of 40 or above)
- **pregnant**

Covid-19 and pregnancy



Headline messages:

- Covid-19 affects pregnant women
- Additional risk factors identified
- Pregnant and postnatal women need evidence-based treatments
- Actively include pregnant and postnatal women in research
- RECOVERY trial has changed clinical practice, including for pregnant women

Covid-19 and pregnancy: RCOG



Royal College of
Obstetricians &
Gynaecologists

Coronavirus (COVID-19) Infection in Pregnancy

Information for healthcare professionals

Version 12: Published Wednesday 14 October 2020

The interim results of the RECOVERY trial demonstrated a significant reduction in 28-day mortality for individuals with COVID-19 requiring oxygen who were given steroid therapy (age-adjusted rate ratio 0.83; 95% CI 0.75–0.93; $P < 0.001$),¹⁰³ and this has been recommended for use in the NHS.¹⁰⁴ The RECOVERY trial protocol for pregnancy recommends prednisolone 40 mg orally once daily, and, in women unable to take oral medicine, hydrocortisone 80 mg intravenously twice daily instead of dexamethasone treatment.^{16 105 106}

Remdesivir is currently subject to a therapeutic alert for pregnancy; it should be avoided unless benefits outweigh risks, following multidisciplinary discussion.¹⁰⁷ Remdesivir is an antiviral medication which has been shown to be associated with a reduction in time to clinical improvement in individuals with severe COVID-19, median 11 versus 15 days, rate ratio 1.32 (95% CI 1.12–1.55).¹⁰⁸

Pregnant women can be enrolled in the RECOVERY trial.

Where therapies or participation in trials are offered, they should also be considered for and offered to pregnant women.

RECOVERY for pregnant women



Site teams

This page contains additional information for RECOVERY site team members. Follow these links for guidance on [randomisation](#) and [how to collect follow-up data](#).

[RECOVERY Privacy Notice for Trial Staff](#)

INTERVENTION INFORMATION

[RECOVERY intervention sheet - aspirin](#)

[RECOVERY intervention sheet - dexamethasone](#) (now only recruiting children)

[RECOVERY intervention sheet - azithromycin](#)

[RECOVERY intervention sheet - tocilizumab](#)

[RECOVERY intervention sheet - assessing patients for risk of transfusion associated circulatory overload \(TACO\) prior to convalescent plasma transfusions](#)

GUIDES FOR SPECIFIC PATIENT GROUPS

[RECOVERY for paediatric patients](#)

[RECOVERY for patients with chronic kidney disease](#)

[RECOVERY for pregnant and breastfeeding women](#)

[RECOVERY and remdesivir](#)

COLLABORATORS' MEETINGS SLIDES

We apologise if you were unable to join the meetings.

[27 October 2020](#)

[26 October 2020](#)

[6 October 2020](#)

[5 October 2020](#)

[14 & 15 September 2020](#)

[3 & 4 August 2020](#)

Pregnancy information document

RANDOMISED EVALUATION OF COVID-19 THERAPY ([RECOVERY](#))

for pregnant and breastfeeding women

Pregnancy leads: Prof Lucy Chappell, Prof Marian Knight

	RECOVERY trial protocol	Adaption for pregnancy
Eligibility	<p>Patients are eligible if all of the following are true:</p> <ul style="list-style-type: none"> i. Hospitalised ii. SARS-CoV-2 infection (clinically suspected or lab confirmed) iii. No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if she were to participate in the trial 	Same eligibility
Interventions	<p>First randomisation part A</p> <ul style="list-style-type: none"> • Azithromycin <p>First randomisation part B</p> <ul style="list-style-type: none"> • Convalescent plasma • Synthetic neutralising antibodies <p>First randomisation part C</p> <ul style="list-style-type: none"> • Aspirin <p>Second randomisation</p> <ul style="list-style-type: none"> • Tocilizumab 	Same interventions
Follow-up/ outcomes	<p>Ascertained at the time of death or discharge or at 28 days after randomisation (whichever is sooner):</p> <ul style="list-style-type: none"> ➤ Vital status (alive/ dead, with date and presumed cause of death, if appropriate) ➤ Hospitalisation status (inpatient/ discharged, with date of discharge, if appropriate) ➤ Use of ventilation (none/ previous/ ongoing, with days of use and type, if appropriate) ➤ Use of renal dialysis or haemofiltration (none/ previous/ ongoing) 	Same follow-up and outcomes, with addition of UKOSS COVID-19 case number (for pregnancy and baby information) to allow later data linkage
		Adaptions for breastfeeding
		The same interventions should be used. UKOSS COVID-19 case number added if available.

Eligibility = same

2.1 Eligibility

Patients are eligible for the study if all of the following are true:

- (i) Hospitalised
- (ii) SARS-CoV-2 infection (clinically suspected¹ or laboratory confirmed)
- (iii) No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial

- No criterion for 'requiring oxygen'

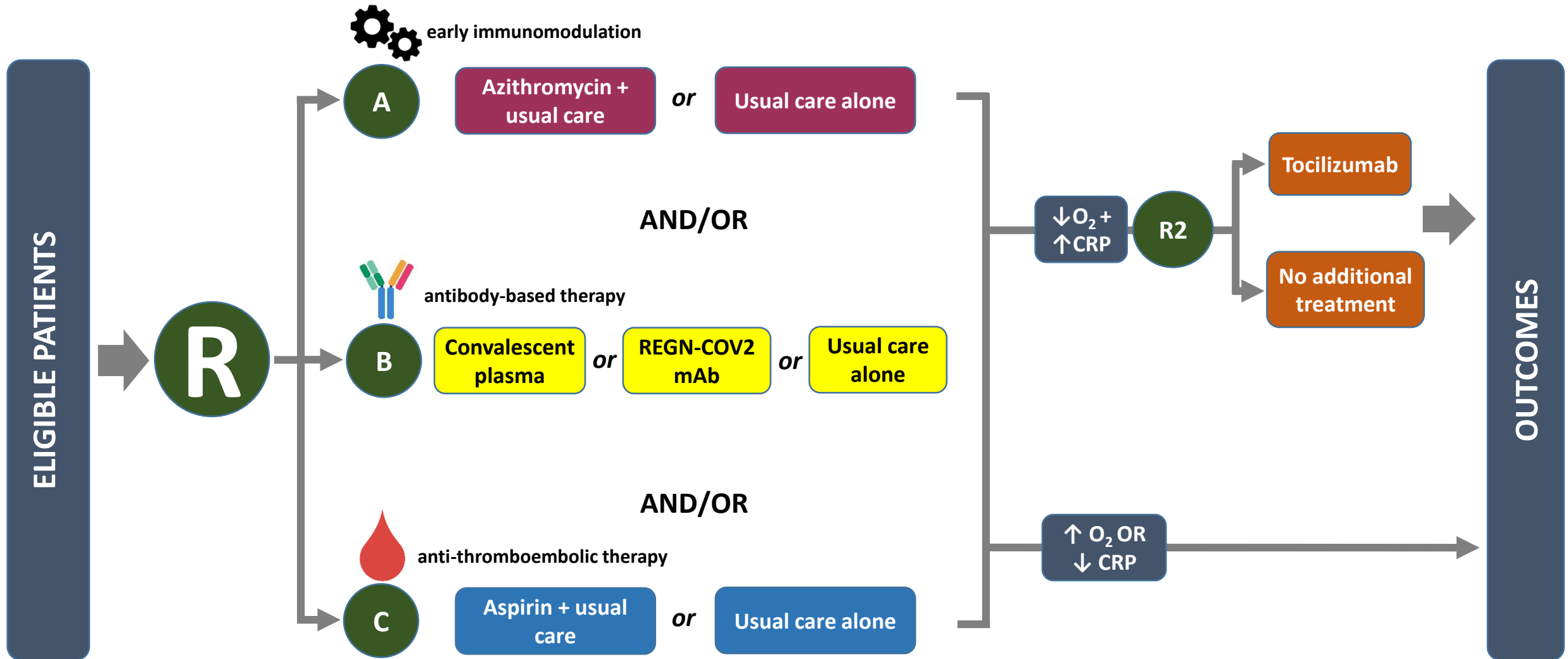
Offer the RECOVERY trial if...



- Are you uncertain about the benefits of treatment or not for this woman, and whether it might 'treat' or prevent deterioration?
- If you are uncertain, then provide the trial information to the woman, offer the trial and make a shared decision.
- **For any woman reportable to UKOSS, ask yourself whether you can offer her participation in RECOVERY**

Interventions = the same

Design



Aspirin 150mg daily

Aspirin: Aspirin is widely used for the prevention of pre-eclampsia in pregnant women at increased risk of the disease. A recent Cochrane meta-analysis on this topic included seventy-seven trials (40,249 women) taking aspirin at doses between 60 and 150mg daily.[12] In most trials, aspirin was started from 12 weeks' gestation, although a more recent meta-analysis has reported eight trials (1426 women) in which aspirin was initiated in the first trimester.[13] In light of the clear evidence of effectiveness, 75-150mg aspirin is recommended for pre-eclampsia prophylaxis in NICE guidelines for management of hypertension in pregnancy (NG133), and in the NHS England document 'Saving Babies' Lives for women at increased risk of placental dysfunction disorders.[14, 15] There is some ongoing uncertainty as to the optimal dose (75mg vs. 150mg) for pre-eclampsia prophylaxis, but both doses are in widespread clinical use in pregnancy in the UK for these indications and in other conditions (e.g. in pregnant women with antiphospholipid syndrome). Aspirin can be given to pregnant women of any gestation or to breastfeeding women in the RECOVERY trial.

Follow-up = the same, + linkage



Nuffield Department of
POPULATION HEALTH



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Search (e.g. Randomisation)

You are here: [UKOSS](#) / [Current Surveillance](#) / COVID-19 in Pregnancy

COVID-19 in Pregnancy



Key points

- Covid-19 is an infectious disease caused by a new strain of coronavirus.
- Covid-19 had not been detected in humans before the outbreak in December 2019.
- As the virus is new, little is known about its effect on certain groups of people, including pregnant women.

Surveillance period

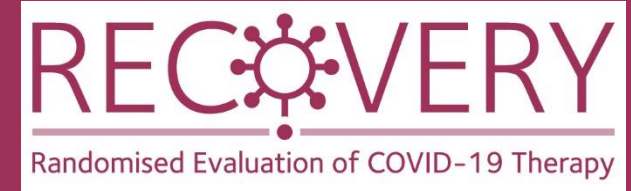
1st March 2020 – 31st March 2021

Background

On this page

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- [Surveillance period](#)
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- [Objective](#)
- [Research questions](#)
- [Case definition](#)
- [Funding](#)
- [Ethics committee approval](#)
- [Study registration](#)
- [Lead investigator](#)
- [Download the Data Collection Form \(DCF\)](#)
- [References](#)

Update on progress



- 160 pregnancy leads identified, supported by research midwives
- Midwife champions on board
- 33 antenatal women recruited and more postpartum women

Update from UKOSS this week



Nuffield Department of
POPULATION HEALTH
Medical Sciences Division



Notifications by week



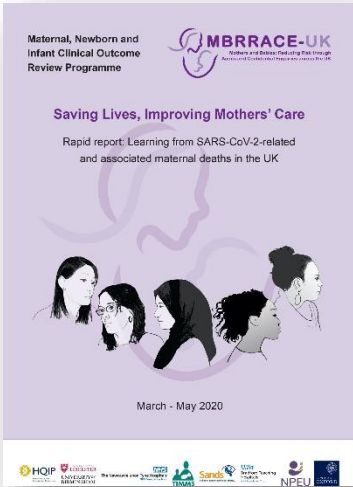
ICNARC data (critical care)

ICNARC report on COVID-19 in critical care:
England, Wales and Northern Ireland
13 November 2020

Table 2. Patient characteristics: medical history

Medical history	Patients with confirmed COVID-19	
	Admitted from 1 Sep (N=4035)	Admitted up to 31 Aug (N=10,910)
Very severe comorbidities *, n (%) [N=3645]		
Cardiovascular	33 (0.9)	70 (0.6)
Respiratory	47 (1.3)	123 (1.1)
Renal	67 (1.8)	186 (1.7)
Liver	28 (0.8)	51 (0.5)
Metastatic disease	28 (0.8)	59 (0.5)
Haematological malignancy	67 (1.8)	212 (2.0)
Immunocompromise	158 (4.3)	386 (3.6)
Body mass index *, n (%) [N=3514]		
<18.5	29 (0.8)	79 (0.8)
18.5-<25	694 (19.7)	2637 (25.4)
25-<30	1150 (32.7)	3563 (34.4)
30-<40	1256 (35.7)	3259 (31.4)
≥40	385 (11.0)	828 (8.0)
CPR within previous 24h, n (%) [N=3726]		
In the community	24 (0.6)	50 (0.5)
In hospital	27 (0.7)	76 (0.7)
Prior hospital length of stay [N=3921]		
Mean (SD)	2.7 (7.6)	2.5 (6.2)
Median (IQR)	1 (0, 3)	1 (0, 3)
Currently or recently pregnant, n (% of females aged 16-49) [N=288]		
Currently pregnant	29 (10.1)	29 (3.7)
Recently pregnant (within 6 weeks)	14 (4.9)	41 (5.2)
Not known to be pregnant	245 (85.1)	718 (91.1)

Recognition of severe illness



A woman in her third trimester of pregnancy presented to the Emergency Department with a one week history of symptoms of COVID-19. Her observations were documented using a National Early Warning Score (NEWS) and not a modified early obstetric warning score (MEOWS). She had a respiratory rate of 36 but this was not recognised as significant. Her first review by a member of obstetric staff was eleven hours after she attended, when a junior obstetrician identified no obstetric concerns. She deteriorated a few days later and was documented to need high dependency or intensive care but no beds were available in either high dependency or intensive care areas. Her care was discussed with a consultant obstetrician at the time of her deterioration and a decision made for a caesarean birth. Following the birth, it was again noted that no beds were available and she was transferred back to a general ward where she deteriorated. She was intubated and transferred to the intensive care unit but her condition continued to worsen and she died a few days later.

Ensure all pregnant or post-partum women with COVID-19 receive multidisciplinary team care and obstetric leadership with daily review. This is essential in order to ensure timely recognition of deterioration, early assessment of the need for iatrogenic birth to help respiratory function and identification of postnatal complications.

Next steps

- Anticipate ongoing new cases over coming weeks
- Check team (and new doctors) are ready for recruitment
- Talk to physicians in main hospital providing care for pregnant women
- Link with main RECOVERY research teams
- Think through pathways for notification of cases
- Use UKOSS as prompt to help (and for outcomes)
- Embed into usual practice
- Offer trial

Q&A