

# Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

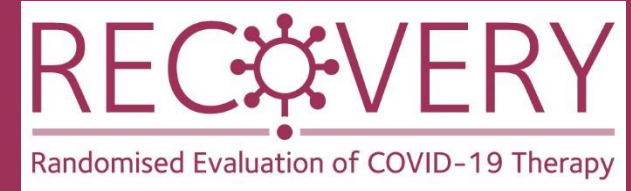
**Collaborators' Meeting**

**26<sup>th</sup> April 2021**

# Agenda

1. Introductions
2. Update on progress
3. REGN-COV2
4. Dimethyl fumarate
5. Baricitinib
6. New international arms
7. Trial procedures
8. Pregnancy update
9. Q&A

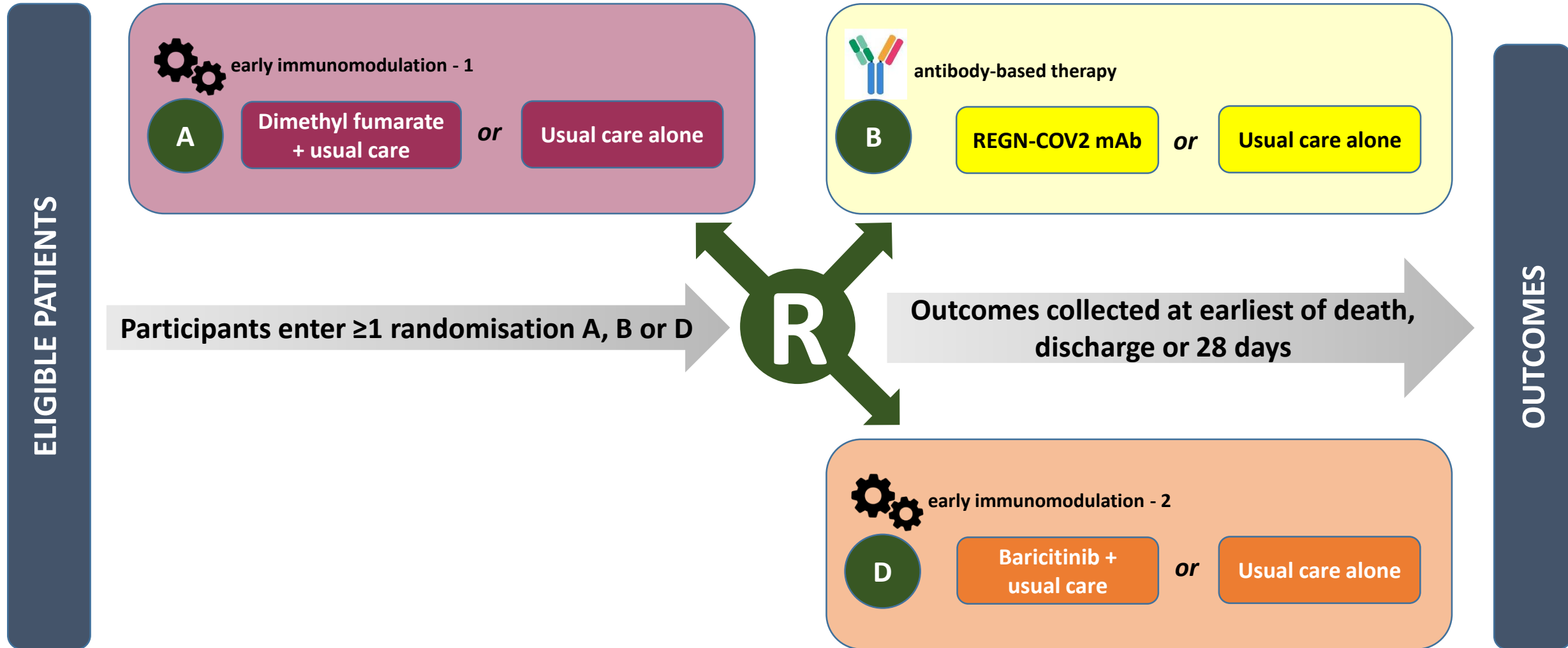
# Introductions



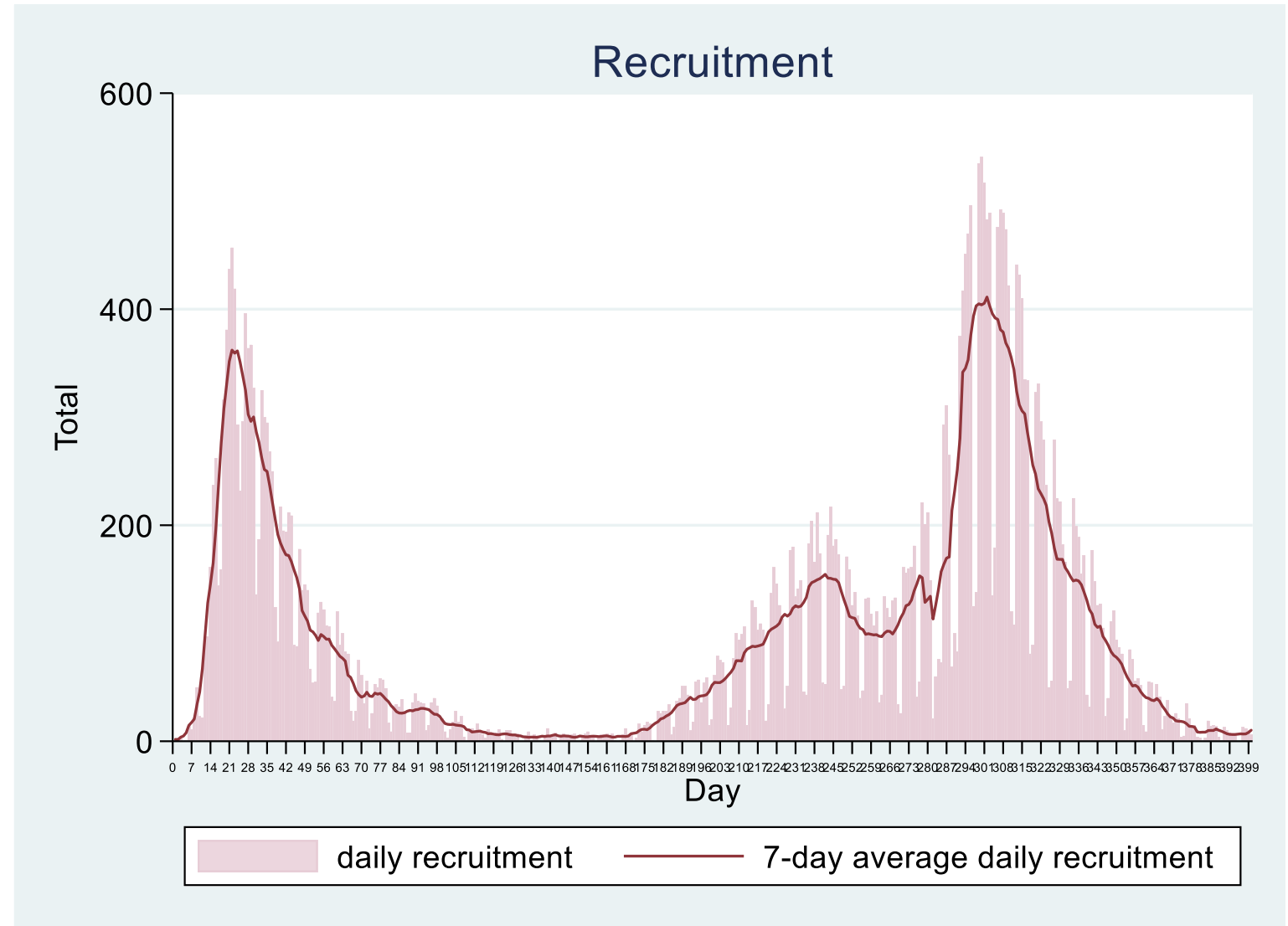
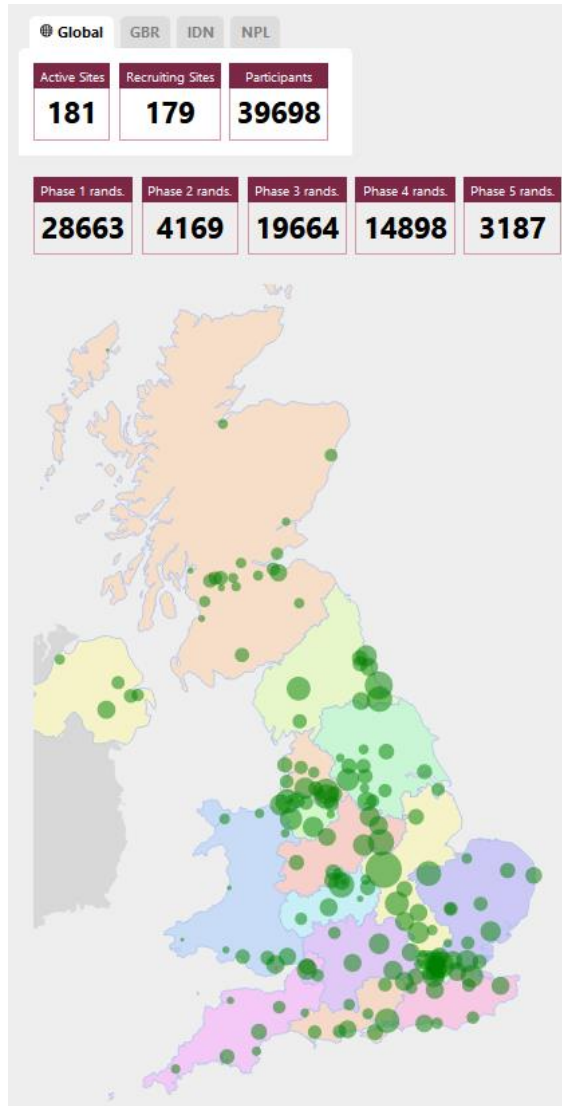
- One of the central study team will talk to the agenda
- If you have questions please enter them into the “Q&A” on the right side of your screen.
- Questions may be answered directly or to the whole group

# PROGRESS UPDATE

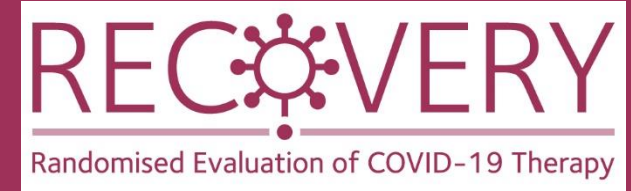
# Current design (adults)



# Recruitment by site and by time



# Current numbers in comparisons



- REGN-COV2 vs usual care: ~9700
- Baricitinib vs usual care: ~3200
- Dimethyl fumarate vs usual care: 70

# Recruitment



- Recruitment will be a challenge over the coming weeks
- Many staff will be returning to previous research studies, but please do ensure that your site continues to have a strategy to identify, invite and recruit patients presenting with COVID-19
- It remains to be seen whether there will be a 'third wave' in the summer, but RECOVERY will remain open



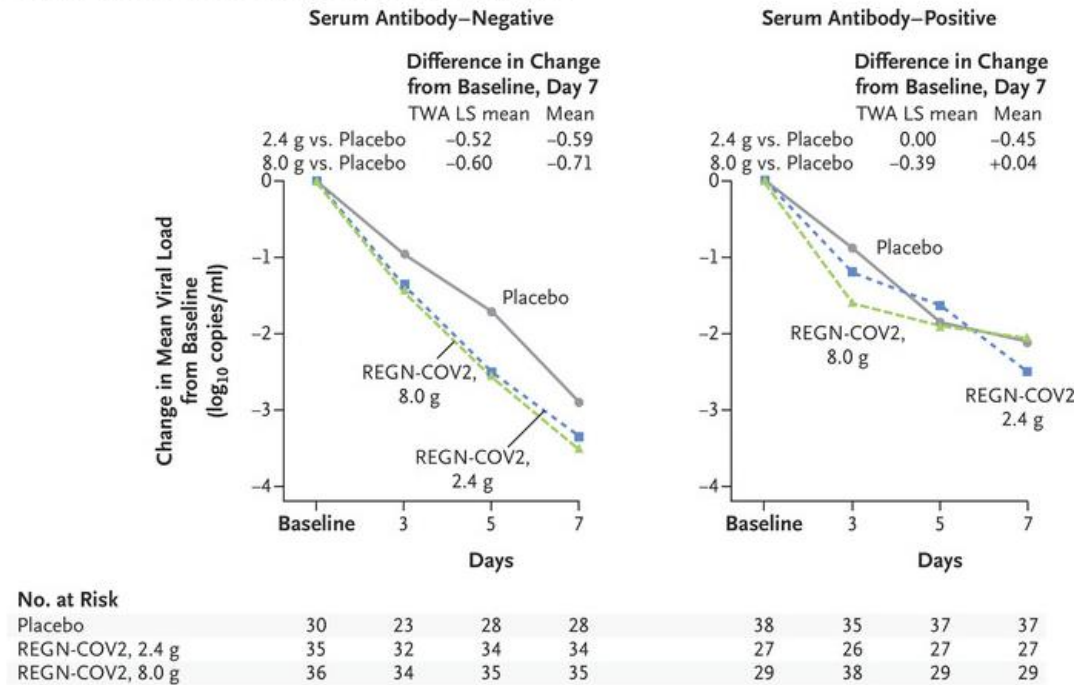
**REGN-COV2**

- 9700 people in comparison to date
- Other data on REGN-COV2 suggests the biggest effect might be expected in antibody negative patients (but these cannot be identified reliably on admission)
- Original aim was to recruit 12,000 participants; currently under review

# REGN-COV2 in outpatients

- Data presented in *NEJM* recently
  - 275 patients with PCR-proven SARS-CoV-2 infection not in hospital
  - Randomised between placebo, 2.4g or 8g (RECOVERY dose) of REGN-COV2 (1:1:1)
  - Key outcome: viral load

B Viral Load over Time According to Baseline Antibody Status



# Serum samples

- **All** participants entering REGN-COV2 comparison need to have serum sample collected prior to randomisation
- Must be taken for all participants in that comparison (regardless of allocation)
- **Please check whether any samples have not been returned to the central lab**

**DIMETHYL FUMARATE**

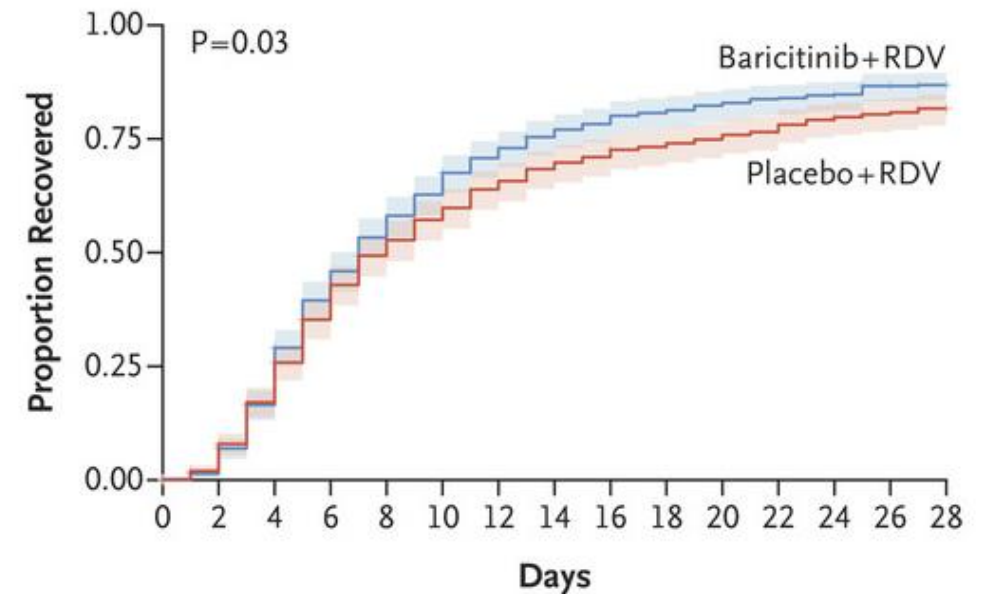
# Dimethyl fumarate

- Recently added to protocol and has been piloted at some sites
- Includes extra data collection on:
  - $S/F_{94}$  (measurement of oxygenation function of lungs)
  - Lab results
  - Tolerability of DMF
- Sites can still express an interest in participating in this arm

**BARICITINIB**

# Baricitinib in COVID-19

- JAK/STAT system is key to immune activation so modulating it may be beneficial
- Data from ACTT-2 show quicker time to recovery

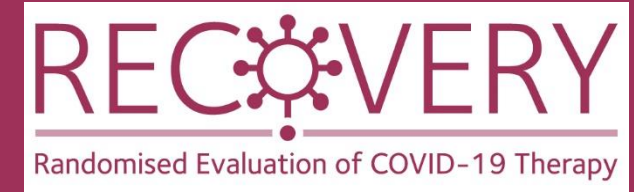


## No. at Risk

Baricitinib+RDV	515	497	418	302	233	186	145	121	107	95	87	80	76	63	30
Placebo+RDV	518	495	417	322	251	211	178	156	143	131	123	115	102	92	44



# Baricitinib in COVID-19: COV-BARRIER



- 1525 patients hospitalised with COVID-19 and at least one marker of inflammation (but not receiving invasive mechanical ventilation)
  - 79% on corticosteroids
- Randomised between baricitinib 4mg once daily and placebo
- Primary outcome: Progression to ventilation or death within 28 days

# Baricitinib in COVID-19: COV-BARRIER



- Trial results announced on 8 April:
  - Non-significant reduction in primary outcome:
    - aOR 0.85; 95% CI 0.67 – 1.08
  - Reduction in death (secondary outcome): 162 deaths in total
    - 8.1% vs 13.1%: HR 0.57, 95% CI 0.41 – 0.78
  - Reassuring safety data: similar proportions with SAEs (14.7% vs 18.0%)
    - Serious infection 8.5% vs 9.8%
    - VTE 2.7% vs 2.5%

# PROTOCOL V15.0

# Protocol V15.0



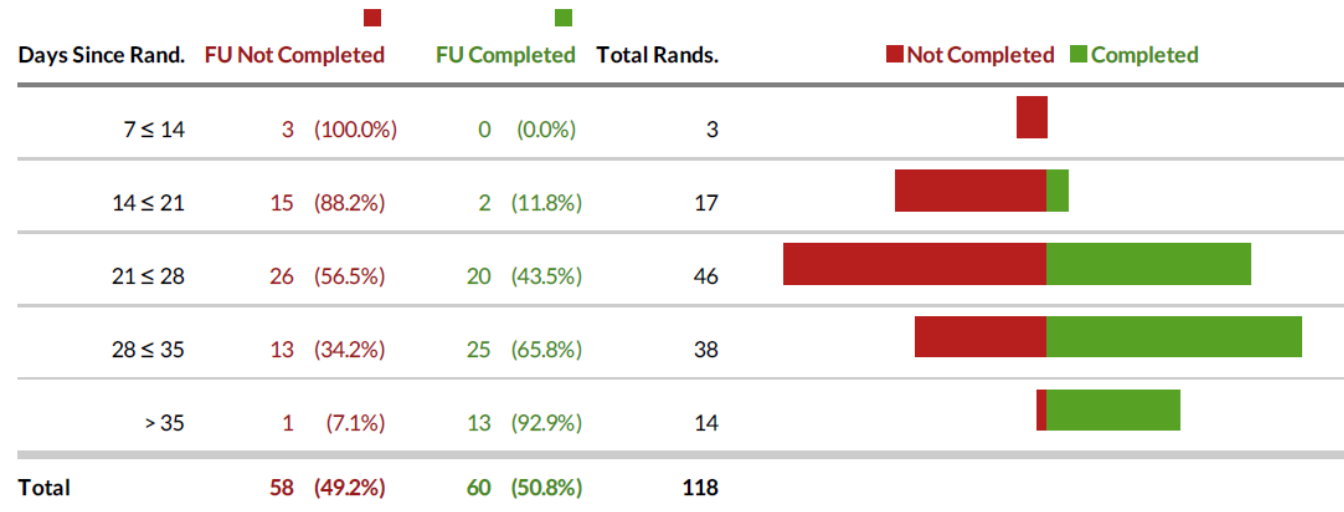
- Officially removes aspirin and colchicine from protocol
- Adds two new arms:
  - Infliximab (single dose 5 mg/kg IV)
  - High-dose dexamethasone (20mg for 5d then 10mg for 5d)
- New arms being started at international sites:
  - Would delay completion of baricitinib
  - Removal of aspirin and colchicine leaves no IMPs for international sites
  - Will be brought back to UK if another wave does occur

# TRIAL PROCEDURES

# Completeness of follow-up

- Weekly reminders highlighting participants randomised >28 days ago without complete form

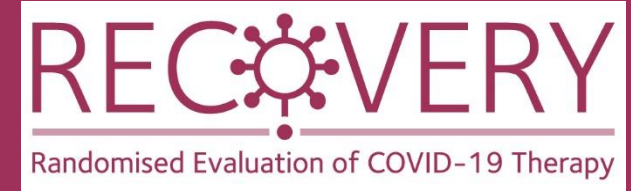
## Follow-up form completion summary



# Baseline samples

- Please don't forget baseline samples for participants in REGN-COV2 comparison!
- These will be key to interpreting the results

# 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 all your support to date and please don't forget RECOVERY!



# Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

**Collaborators' Meeting for Pregnancy**

**26 April 2021**

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

BMJ: first published as 10.1136/bmj.m33

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BMJ Yale

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The incidence, characteristics and outcomes of pregnant women hospitalized with symptomatic and asymptomatic SARS-CoV-2 infection in the UK from March to September 2020: a national cohort study using the UK Obstetric Surveillance System (UKOSS)

Covid-  
Patrick  
doi: ht

Maternal, Newborn and  
Infant Clinical Outcome  
Review Programme



**MBRRACE-UK**  
Mothers and Babies: Reducing Risk through  
Audits and Confidential Enquiries across the UK

Saving Lives, Improving Mothers' Care

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

Check for updates

<sup>1</sup> National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, UK

<sup>2</sup> Institute of Applied Health Research, University of Birmingham, Birmingham, UK

<sup>3</sup> UK Obstetric Surveillance System

### Include pregnant women in research—particularly covid-19 research

Adapting interventions and changing attitudes will drive scientific progress

Marian Knight,<sup>1</sup> R Katie Morris,<sup>2</sup> Jenny Furniss,<sup>3</sup> Lucy C Chappell<sup>1</sup>

The UK Confidential Enquiries into Maternal Deaths have repeatedly highlighted inequities in the medical treatment of pregnant and postpartum women, noting or breastfeeding allows safety concerns to be allayed for women, their families, and healthcare professionals.

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<sup>1,\*</sup>; Sascha Ellington, PhD<sup>1,\*</sup>; Penelope Strid, MPH<sup>1</sup>; Romeo R. Galang, MD<sup>1</sup>; Titilope Oduyebo, MD<sup>1</sup>; Van T. Tong, MPH<sup>1</sup>; Kate R. Woodworth, MD<sup>1</sup>; John F. Nahabedian III, MS<sup>1</sup>; Eduardo Azziz-Baumgartner, MD<sup>1</sup>; Suzanne M. Gilboa, PhD<sup>1</sup>; Dana Meaney-Delman, MD<sup>1</sup>; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team

Research

JAMA Pediatrics | Original Investigation

## Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection The INTERCOVID Multinational Cohort Study

José Villar, MD; Shabina Ariff, MD; Robert B. Gunier, PhD; Ramachandran Thiruvengadam, MD; Stephen Rauch, MPH; Alexey Kholin, MD; Paola Roggero, PhD; Federico Prefumo, PhD; Marynéa Silva do Vale, MD; Jorge Arturo Cardona-Perez, MD; Nerea Maiz, PhD; Irene Cetin, MD;

## RESEARCH

OPEN ACCESS

Check for updates

FAST TRACK

EDITORIALS

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

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

BMJ: first published as 10.1136/bmj.m33

# Pregnant women – moderate risk group

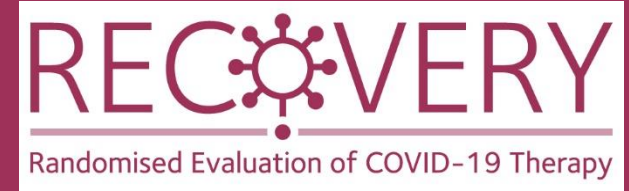
## People at moderate risk (clinically vulnerable)

People at moderate risk from coronavirus include people who:

- are 70 or older
- have a lung condition that's not severe (such as asthma, COPD, emphysema or bronchitis)
- have heart disease (such as heart failure)
- have diabetes
- have chronic kidney disease
- have liver disease (such as hepatitis)
- have a condition affecting the brain or nerves (such as Parkinson's disease, motor neurone disease, multiple sclerosis or cerebral palsy)
- have a condition that means they have a high risk of getting infections
- are taking medicine that can affect the immune system (such as low doses of steroids)
- are very obese (a BMI of 40 or above)
- are **pregnant** – see [advice about pregnancy and coronavirus](#)

Unlike people at high risk, you will not get a letter from the NHS.

# Covid-19 and pregnancy: headlines



- Covid-19 affects pregnant women
- Additional risk factors previously identified (ethnic minority groups, increasing gestation, higher maternal age, high BMI, pre-existing comorbidities)
- Impact on preterm birth continues to be major impact
- Ongoing evaluation of increased maternal risk (ICU admission and maternal morbidity) and increased perinatal risk (placentitis and stillbirth)
- RECOVERY trial is one of few trials to include pregnant women, and 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 13: Published Friday 19 February 2021

- Corticosteroid therapy should be considered for 10 days or up to discharge, whichever is sooner; for women who are unwell with COVID-19 and requiring oxygen supplementation or ventilatory support. One suggested steroid regimen is:
  - If steroids are not indicated for fetal lung maturity, oral prednisolone 40 mg once a day, or IV hydrocortisone 80 mg twice daily, for 10 days or until discharge, whichever is sooner.
  - If steroids are indicated for fetal lung maturity, intramuscular dexamethasone 6 mg every 12 hours for four doses, then oral prednisolone 40 mg once a day, or IV hydrocortisone 80 mg twice daily, to complete a total of 10 days or until discharge, whichever is sooner.

- The interleukin-6 receptor antagonist (anti-IL6) tocilizumab has been shown to improve outcomes, including survival, in hospitalised patients with hypoxia (oxygen saturation below 92% on air or requiring oxygen therapy) and evidence of systemic inflammation (C-reactive protein at or above 75 mg/l). Although data for the use of tocilizumab in pregnancy in this situation are limited, there is currently no compelling evidence that tocilizumab is teratogenic or fetotoxic. For women meeting the criteria above (hypoxic with systemic inflammation), the use of tocilizumab should be considered. It is recommended that any decision to treat with anti-IL6 agents should be taken by an MDT to include obstetric and infection specialists, and given if the benefits outweigh the risks.

- Other therapies are being investigated for the management of COVID-19, and pregnant women should be offered the opportunity to enrol in clinical trials (such as the RECOVERY trial) for which they are eligible. Hydroxychloroquine, lopinavir-ritonavir and azithromycin have been shown to be ineffective in treating COVID-19 infection and should not be used for this purpose.

# 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 - colchicine](#)  
[RECOVERY intervention sheet - aspirin](#)  
[RECOVERY intervention sheet - baricitinib](#)  
[RECOVERY intervention sheet - tocilizumab](#)  
[RECOVERY intervention sheet - dimethyl fumarate](#)

### GUIDES FOR SPECIFIC PATIENT GROUPS

[RECOVERY for paediatric patients](#)  
[RECOVERY for patients with chronic kidney disease](#)  
[RECOVERY for pregnant and breastfeeding women](#)

### COLLABORATORS' MEETINGS SLIDES

We apologise if you were unable to join the meetings.

<a href="#">22 February 2021</a>	<a href="#">23 February 2021</a>
<a href="#">25 January 2021</a>	<a href="#">26 January 2021</a>
<a href="#">4 January 2021</a>	<a href="#">5 January 2021</a>
<a href="#">7 December 2020</a>	<a href="#">8 December 2020</a>

# Pregnancy information document

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

for pregnant and breastfeeding women

Pregnancy leads: Prof Lucy Chappell, Prof Marian Knight

With support of UK Teratology Information Service (Dr Ken Hodson, Medical Director)

	RECOVERY trial protocol	Adaption for pregnancy
<b>Eligibility</b>	Patients are eligible if all of the following are true: 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 they were to participate in the trial	Same eligibility
<b>Interventions</b>	<b>First randomisation part A</b> • Dimethyl fumarate (in some sites) <b>First randomisation part B</b> • Synthetic neutralising antibodies (REGN-COV2) <b>First randomisation part D</b> • <u>Baricitinib</u>	Interventions for pregnant women • Synthetic neutralising antibodies  <i>Not recommended in pregnancy</i> • <i>Dimethyl fumarate</i> • <i>Baricitinib</i>
<b>Follow-up/ outcomes</b>	Ascertained at the time of death or discharge or at 28 days after randomisation (whichever is sooner): ➢ 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 <b>addition of UKOSS COVID-19 case number</b> (for pregnancy and baby information) to allow later data linkage
		<b>Adaptions for breastfeeding</b>
		The same interventions as in pregnancy 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 suspected<sup>1</sup> 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

- Hospitalised, with symptoms (no criterion for 'requiring oxygen')

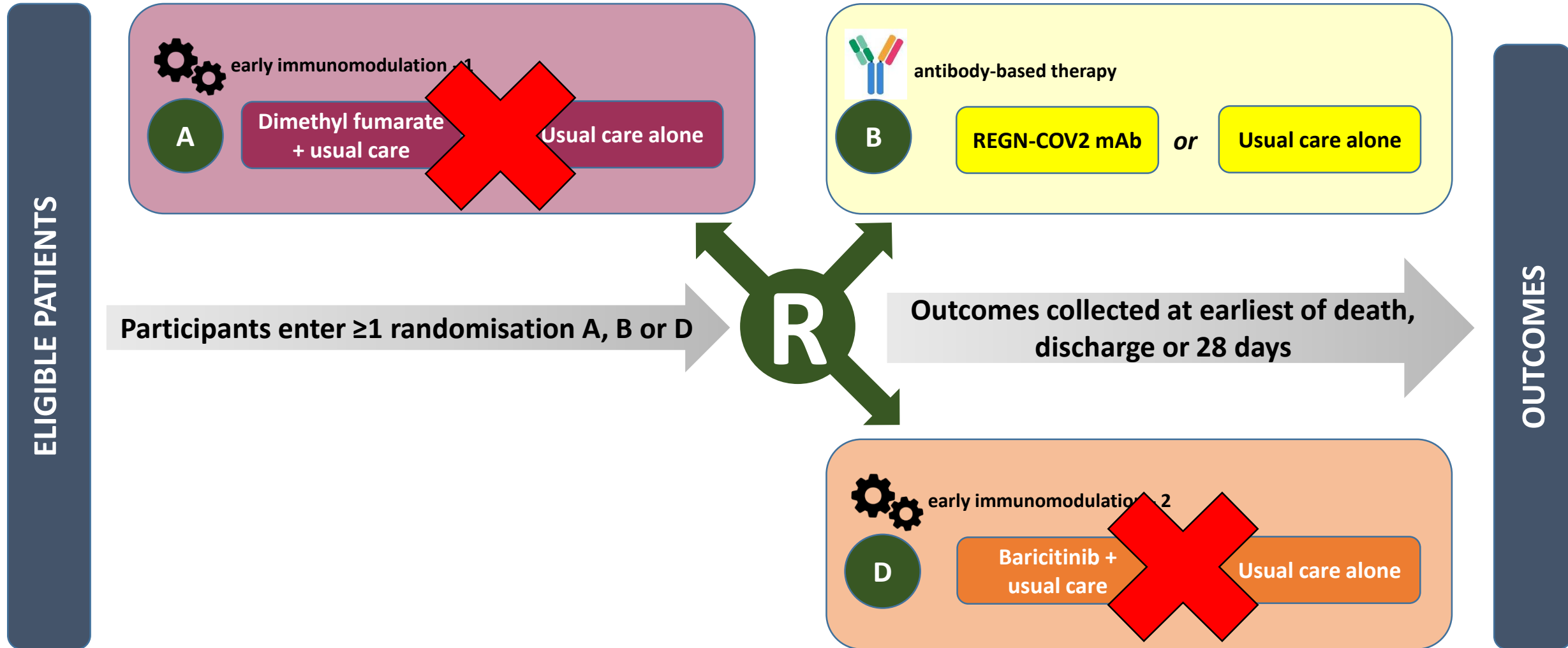
# Offer the RECOVERY trial if...



- 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 = almost the same

# Current design (adults)





# Live infant vaccines possible after REGN

The previous version (V12.1) of the RECOVERY protocol stated: *Pregnant women that are administered REGN10933 and REGN10987 must be advised that live vaccines should be avoided in children with in utero exposure to biologics for at least the first 6 months of life.* This sentence has now been deleted, following review of the biological rationale. The synthetic monoclonal antibodies (REGN10933+REGN10987) bind to the SARS-CoV-2 spike protein on the surface of cells, blocking the interaction between the spike protein and its canonical receptor angiotensin-converting enzyme 2. There are no human protein targets of the Regeneron monoclonal antibodies. This is in contrast to infliximab, a biologic drug implicated in a single case report of a 4 month old infant in London who died of probable disseminated TB following maternal infliximab use in pregnancy and infant BCG vaccination at 3 months of age.[7] Infliximab targets human TNF-alpha, such that if used in later pregnancy, the immune system of the neonate may be compromised, leading to potential systemic disease following administration of live vaccines. Regeneron monoclonal antibodies are similar in type to other immunoglobulins that are commonly given in pregnancy such as anti-D, varicella zoster immunoglobulin etc., for which an advisory warning against live vaccine administration in the infant is not required. Therefore, women do not need to be advised that live vaccines should be avoided in their infant following administration of these synthetic monoclonal antibodies.

# Follow-up = the same, + linkage



Nuffield Department of  
POPULATION HEALTH



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## 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

- [Key points](#)
- [Surveillance period](#)
- [Background](#)
- [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
- **108** antenatal women recruited
- $\approx 20$  (or more) postpartum women

# Thank you



Ashford and St Peter's Hospitals NHS Foundation Trust	Leeds Teaching Hospitals NHS Trust	Oxford University Hospitals NHS Foundation Trust
Barts Health NHS Trust	Liverpool University Hospitals NHS Foundation Trust	Pennine Acute Hospitals NHS Trust
Bolton NHS Foundation Trust	Liverpool Women's NHS Foundation Trust	Royal Berkshire NHS Foundation Trust
Bradford Teaching Hospitals NHS Foundation Trust	Luton and Dunstable University Hospital NHS Foundation Trust	Royal Free London NHS Foundation Trust
Cambridge University Hospitals NHS Foundation Trust	Manchester University NHS Foundation Trust	Sheffield Teaching Hospitals NHS Foundation Trust
Chelsea and Westminster Hospital NHS Foundation Trust	Medway NHS Foundation Trust	Sherwood Forest Hospitals NHS Foundation Trust
Chesterfield Royal Hospital NHS Foundation Trust	Milton Keynes University Hospital NHS Foundation Trust	Shrewsbury and Telford Hospital NHS Trust
Croydon Health Services NHS Trust	NHS Greater Glasgow and Clyde: Glasgow Royal Infirmary	St George's University Hospitals NHS Foundation Trust
Epsom and St Helier University Hospitals NHS Trust	NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital	The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Frimley Health NHS Foundation Trust	NHS Lothian: Royal Infirmary of Edinburgh	United Lincolnshire Hospitals NHS Trust
Guy's and St Thomas' NHS Foundation Trust	North Cumbria Integrated Care NHS Foundation Trust	University College London Hospitals NHS Foundation Trust
Imperial College Healthcare NHS Trust	North Tees and Hartlepool NHS Foundation Trust	University Hospitals Of Leicester NHS Trust
James Paget University Hospitals NHS Foundation Trust	North West Anglia NHS Foundation Trust	Western Sussex Hospitals NHS Foundation Trust
Kettering General Hospital NHS Foundation Trust	Northampton General Hospital NHS Trust	Worcestershire Acute Hospitals NHS Trust
King's College Hospital NHS Foundation Trust	Northumbria Healthcare NHS Foundation Trust	Wye Valley NHS Trust
Kingston Hospital NHS Foundation Trust	Nottingham University Hospitals NHS Trust	



# Update from UKOSS this week



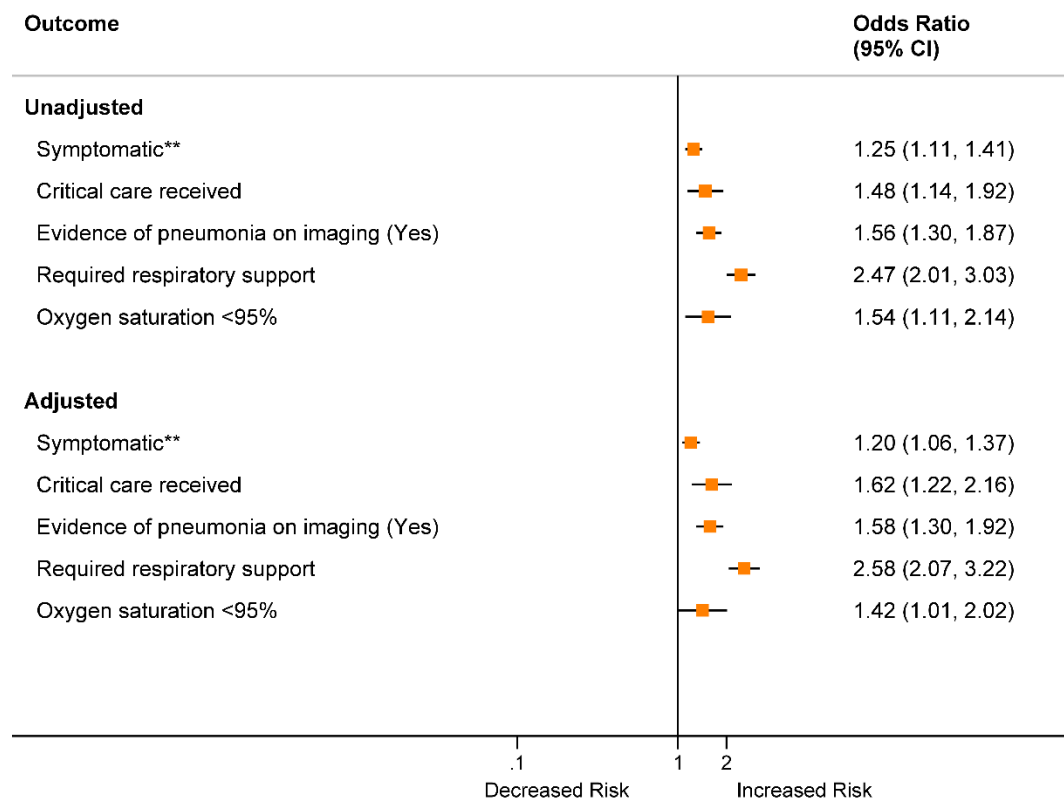
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Medical Sciences Division



## Notifications by week



## Selected respiratory characteristics and outcomes in symptomatic pregnant women admitted to hospital with confirmed SARS-CoV-2 Dec 2020-Feb 2021 compared to Mar-Nov 2020

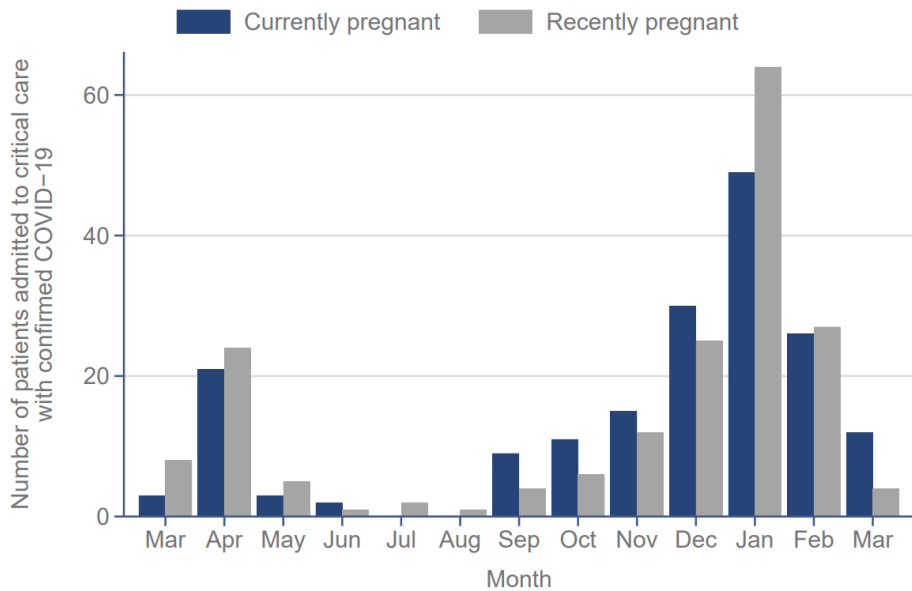


Note: \*\*Odds ratios for symptomatic versus asymptomatic calculated for June 2020-February 2021 when screening was in place  
Adjusted for age, ethnicity, BMI, and selected pre-existing conditions (asthma, hypertension, cardiac disease, and diabetes)

- Pregnant women admitted during the period when the B117 variant became predominant were significantly more likely to be symptomatic
- Symptomatic pregnant women admitted during the period when the B117 variant became predominant were significantly more likely to require respiratory support
- Covid-specific medical therapies were used infrequently, even for women who were critically ill
- Steroids for maternal indication administered to:
  - 7% of symptomatic pregnant women admitted
  - 18% of those who received critical care.
- 3% of symptomatic pregnant women admitted to hospital were recruited to the RECOVERY trial.
- After release of results on dexamethasone from the RECOVERY trial, rates of usage of steroids for maternal indications remained low:
  - 9% of women overall,
  - 23% of those receiving critical care

# ICNARC data (critical care)

## ICNARC report on COVID-19 in critical care: England, Wales and Northern Ireland 26 March 2021

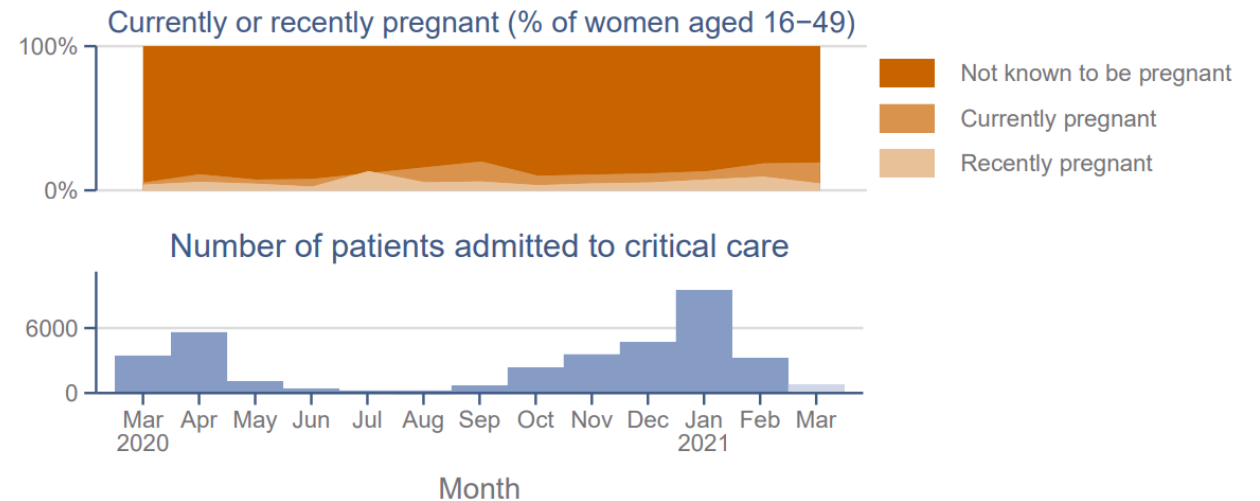


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**Figure 38. Numbers currently and recently pregnant**

Monthly trend in the number of women reported to be currently or recently pregnant on admission to critical care.

Medical history	Patients with confirmed COVID-19	
	Admitted from 1 Sep (N=24,781)	Admitted up to 31 Aug (N=10,927)
Currently or recently pregnant, n (% of females aged 16-49) [N=2157]		
Currently pregnant	151 (7.0)	29 (3.7)
Recently pregnant (within 6 weeks)	142 (6.6)	41 (5.2)
Not known to be pregnant	1864 (86.4)	720 (91.1)



# Feedback from sites

- Low numbers of symptomatic women
- But admissions of symptomatic women continue
- Sites liaising with their main RECOVERY research teams
- Maternity healthcare professionals providing input into care of pregnant women on general wards

## PLEASE:

- Use UKOSS as prompt to help (and for outcomes)
- **Please add UKOSS number to ALL RECOVERY women recruited**
- Embed into usual practice
- Offer trial

# Q&A