Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting

25th & 26th January 2021

Agenda

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1. Introductions
2. Update on progress
3. Tocilizumab
4. Convalescent plasma
5. Colchicine
6. Other trial results
7. Future amendments to the protocol
8. Trial procedures
9. Q&A

Introductions

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- 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

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PROGRESS UPDATE

Current design

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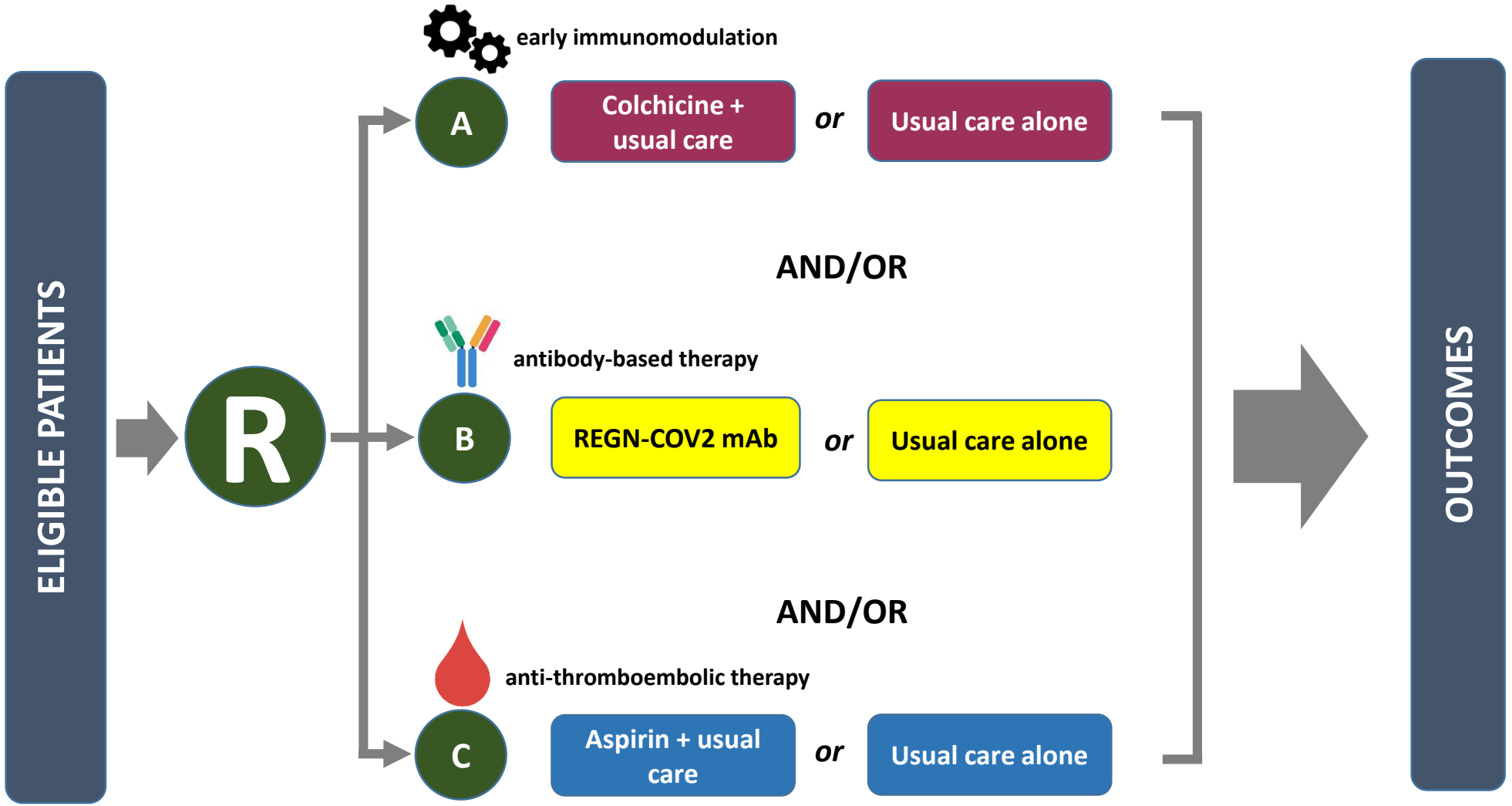

Recruitment by site and by time

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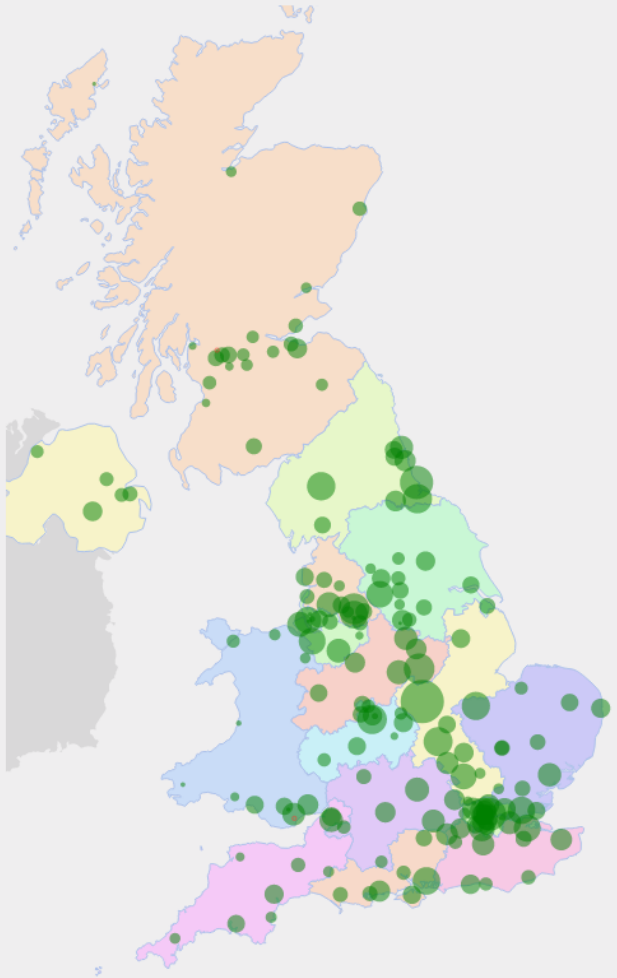
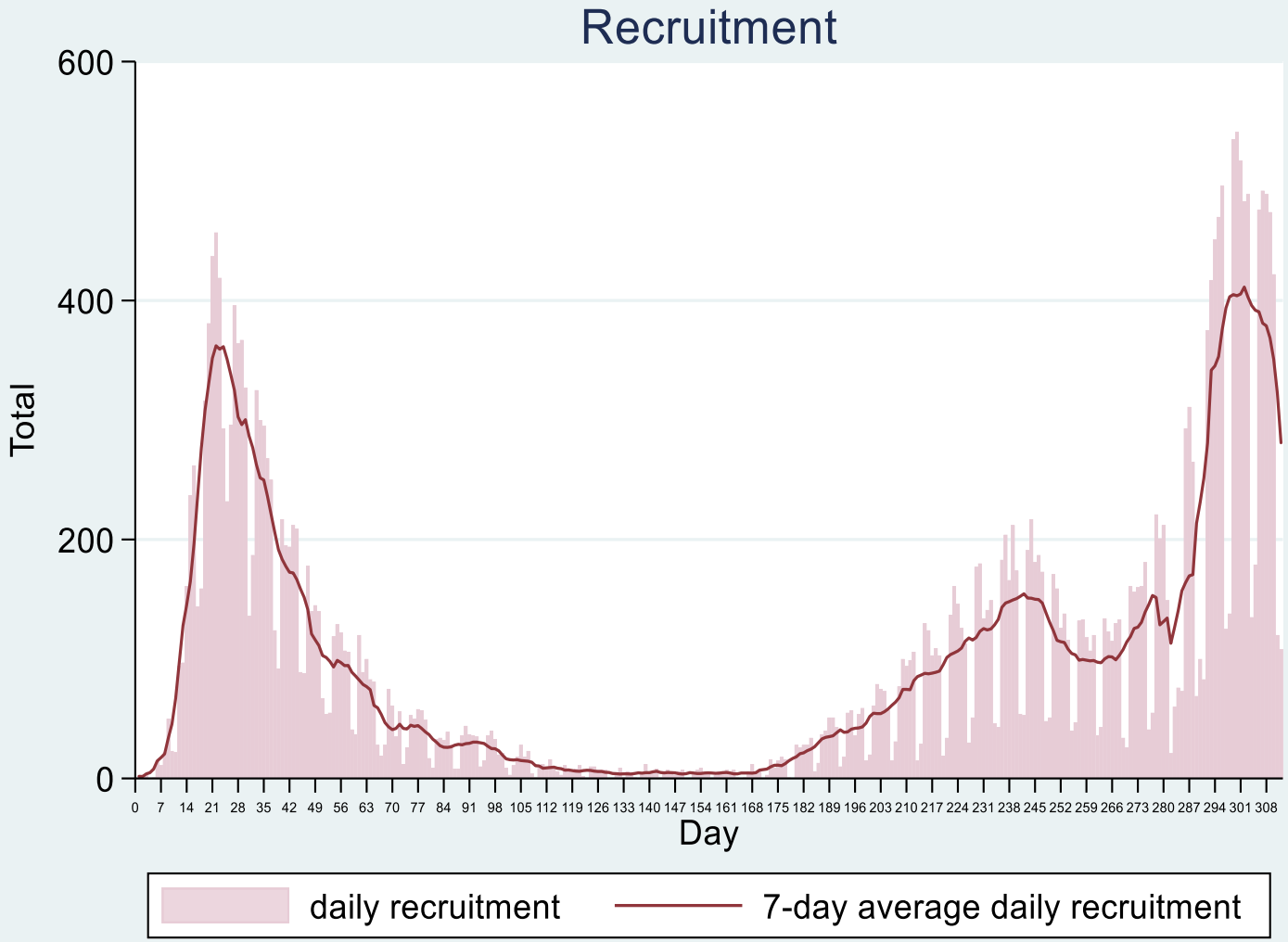
Active Sites	Recruiting Sites	Participants	Phase 2 rands.	Phase 3 rands.	Phase 4 rands.
177	175	31569	4137	15407	9797





Current numbers in comparisons

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- Colchicine *vs* usual care: ~6800
- REGN-COV2 *vs* usual care: ~5500
- Aspirin *vs* usual care: ~9800

Recruitment

- Please continue to prioritise RECOVERY in accordance with its Urgent Public Health Priority 1A status (same as vaccine trials)

- Average recruitment remains at about 10% of all COVID-19 admissions, but with significant variation between regions and sites

- Please let us know how we could support recruitment at your site

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TOCILIZUMAB

Tocilizumab in RECOVERY

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- Recruitment stopped on 25th January after completion of recruitment of 2000 people to tocilizumab and 2000 people to usual care alone

- Follow-up continues

- Use of tocilizumab within NHS should now either be randomisation in REMAP-CAP (where available) or as defined in the CAS alert on 8 January (https://www.cas.mhra.gov.uk/Help/CoronavirusAlerts.aspx)

Tocilizumab in RECOVERY

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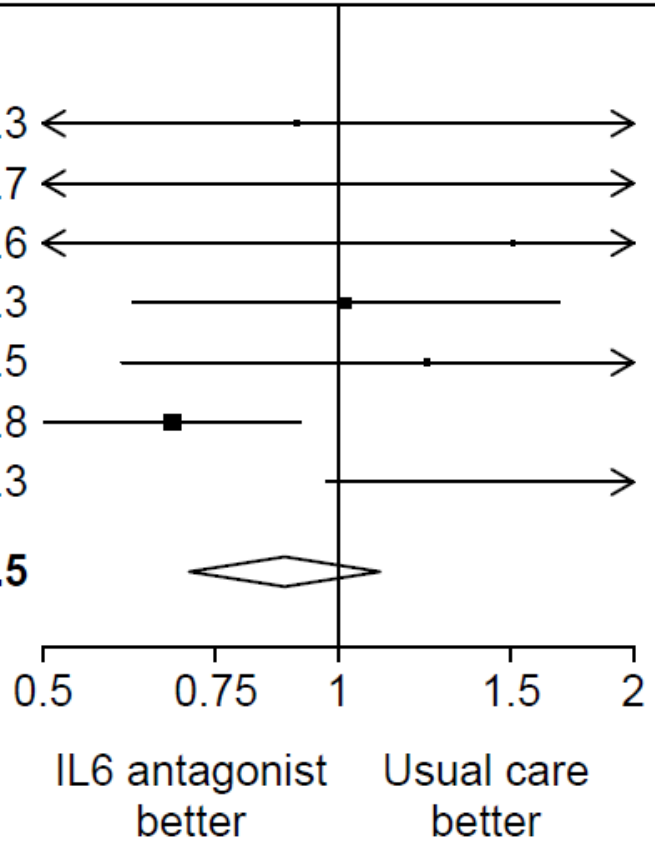
	IL6 antagonist	Usual care	O−E	V	RR (95% CI)
CORIMUNDO−TOCI	7/64 (10.9%)	8/67 (11.9%)	−0.3	3.3	0.91 (0.31−2.65)
RCT−TCZ−COVID−19	2/60 (3.3%)	1/66 (1.5%)	0.6	0.7	2.17 (0.22−21.33)
BACC Bay	9/161 (5.6%)	3/82 (3.7%)	1.0	2.6	1.51 (0.44−5.13)
COVACTA	58/294 (19.7%)	28/144 (19.4%)	0.3	15.3	1.02 (0.62−1.68)
EMPACTA	26/249 (10.4%)	11/128 (8.6%)	1.6	7.5	1.23 (0.60−2.52)
REMAP−CAP	108/395 (27.3%)	142/397 (35.8%)	−16.7	42.8	0.68 (0.50−0.91)
TOCIBRAS	14/65 (21.5%)	6/64 (9.4%)	3.9	4.3	2.51 (0.97−6.50)
All trials	**224/1288 (17.4%)**	**199/948 (21.0%)**	**−9.6**	**76.5**	**0.88 (0.70−1.10) p=0.27**



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CONVALESCENT PLASMA

Convalescent plasma

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- Recruitment stopped on 15th January on recommendation of the Data Monitoring Committee

  "For convalescent plasma, we saw no convincing evidence that further recruitment would provide conclusive proof of worthwhile mortality benefit either overall or in any pre-specified subgroup."

- This decision was based on about 1800 deaths, but due to speed of recruitment there are several thousand participants without complete follow-up

- Analysis of recipient and donor samples also continues

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REGN-COV2

REGN-COV2

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- Nearly 5000 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)
- Regeneron have agreed to provide an additional 4000 doses so comparison can expand to 6000 vs 6000 (in order to recruit sufficient antibody negative patients)

Antibody levels from first 8295 participants

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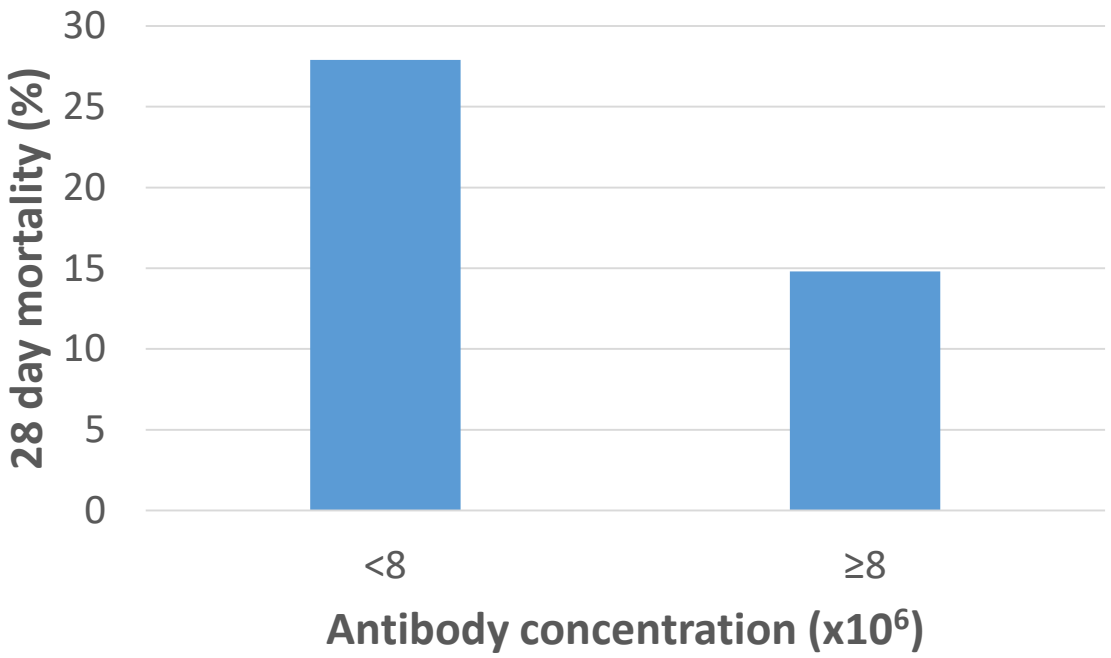
Baseline antibody level and risk of death



Baseline antibody level by arm

Recipient concentration	REGN-COV2	Usual care
Available	58%	55%
Missing	42%	45%

Serum samples

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- **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**

Antibody-based therapies and vaccination

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- Receipt of ‘passive’ antibodies (ie, convalescent plasma or REGN-COV2) might reduce efficacy of vaccination

- JCVI have not made a determination yet, but US CDC does recommend a 90-day period in-between receiving passive antibodies and being vaccinated

- We have asked you to:
  - Inform current participants of this (and include information in discharge summaries)
  - Send text of letter to patients who have received antibody-based therapy in last 90 days

- We will add information to next version of PIS/ICF

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COLCHICINE

Colchicine

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- COLCORONA trial randomised 4488 outpatients with COVID-19 between colchicine (similar dosing to RECOVERY) and placebo
- Primary outcome: hospitalisation or death
- Preliminary results suggest non-significant 21% reduction in risk
  - In subgroup of 4159 patients with positive nasopharyngeal PCR test the results are significant
  - In this subgroup, hospitalisation reduced by 25% and death by 44%

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OTHER RECENT TRIAL RESULTS

Anticoagulation

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- Recent report from REMAP-CAP says that therapeutic anticoagulation is of benefit among patients not requiring organ support

- Results contrast with those among sicker patients (requiring organ support) where trials stopped for futility or harm

- No impact on RECOVERY aspirin comparison (pending full results)

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NEXT VERSION OF PROTOCOL

Baricitinib in COVID-19

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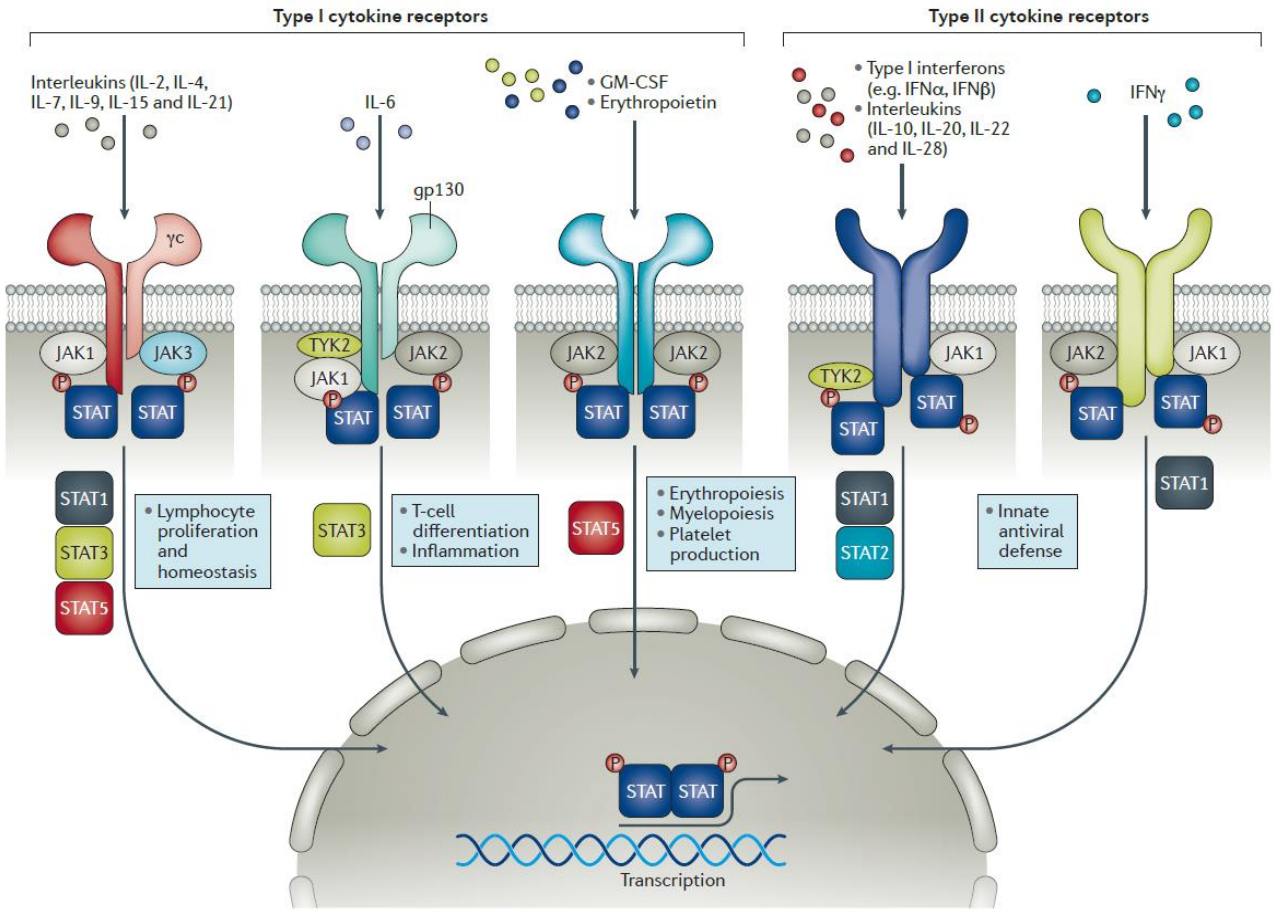
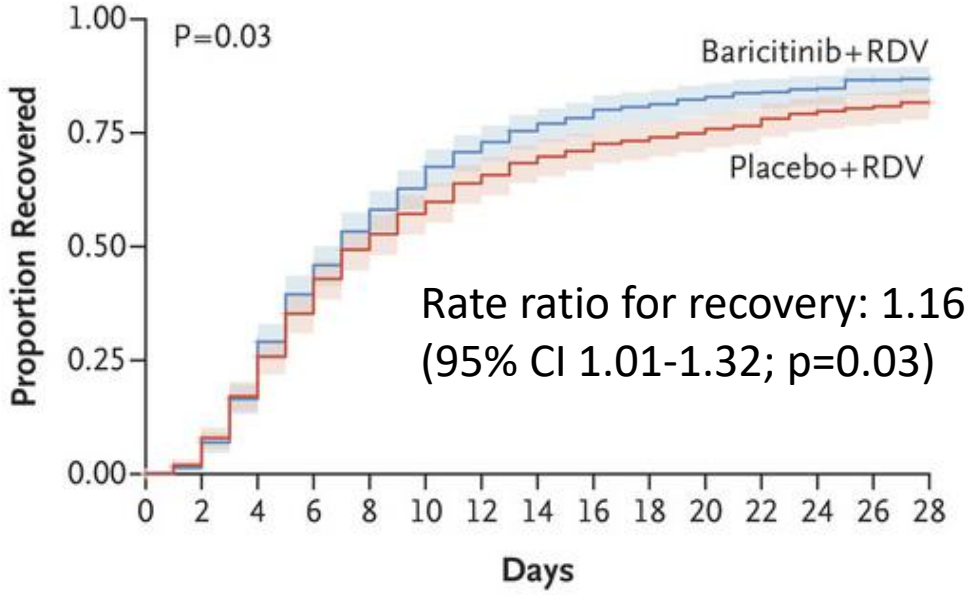
- JAK proteins work with STAT proteins to transmit cytokine signals from outside the cell to the nucleus and hence gene transcription

- Therefore inhibiting JAK/STAT might helpfully modify the immune response



ACTT-2 results



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

Outcome	Rate ratio (95% CI)
Mortality	0.65 (0.39-1.09)
Death or IMV	0.69 (0.50-0.95)
IMV	0.64 (0.44-0.93)

Safety:
SAEs in 16.0% *vs* 21.0% (p=0.03)

Next design (adults)

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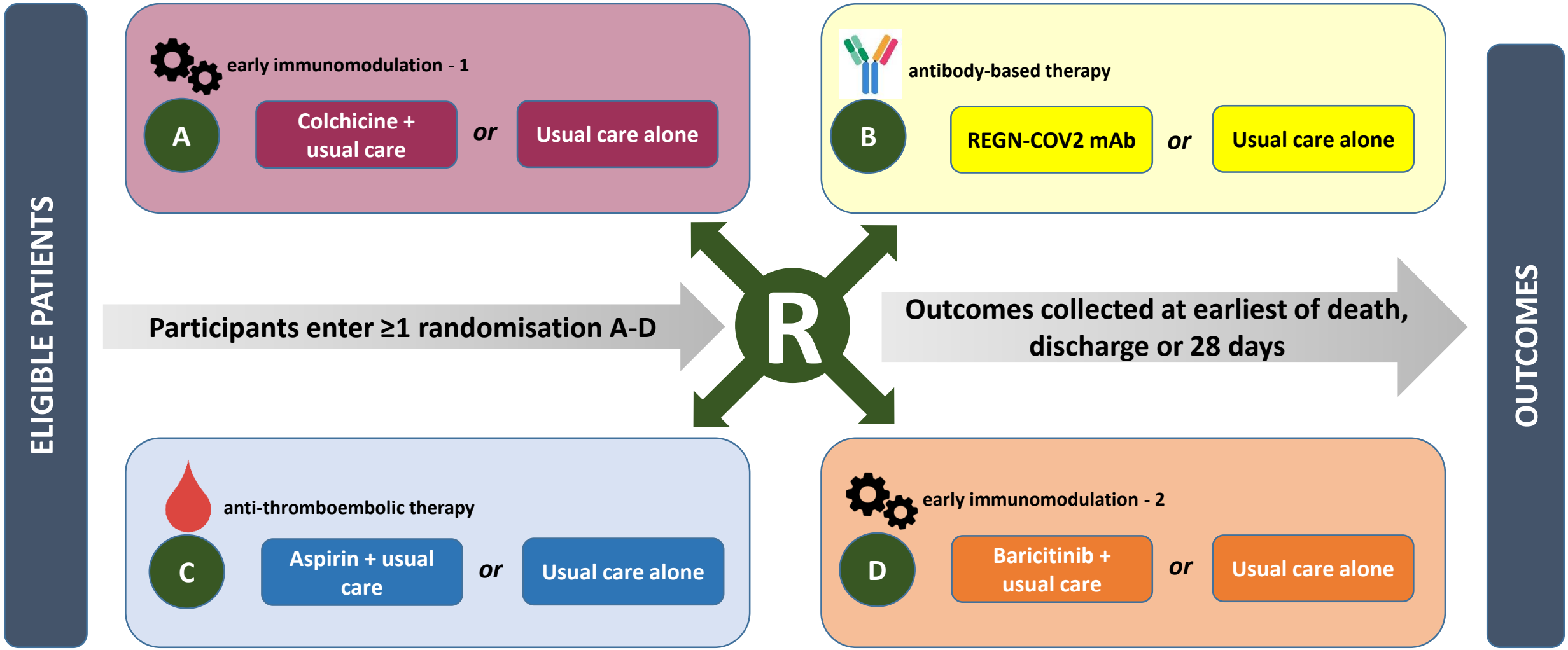

Baricitinib in RECOVERY

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- Dose: 4 mg (one tablet) once daily by mouth/NG tube for 10 days (or until discharge if sooner)

- Contraindicated in pregnancy → all women of child-bearing potential will now require pregnancy test (or if unavailable/declined will be excluded from baricitinib and colchicine arms)

- Should not be given if tocilizumab already given *or* definitely planned in next 24 hours

Baricitinib in RECOVERY

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- **Contraindications:**
  - Pregnancy
  - eGFR <15 mL/min/1.73m^2 (including those on dialysis/haemofiltration)
  - Neutrophil count <0.5 x10^9/L
  - Active TB infection
  - Has received tocilizumab or planned in next 24 hours

- **Cautions:**
  - Dose reduction for kidney impairment
    - eGFR ≥30 <60 mL/min/1.73m^2: 2 mg once daily
    - eGFR ≥15 <30 mL/min/1.73m^2: 2 mg alternate days
  - Dose should be halved if taking probenecid

Anakinra in RECOVERY

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- Anakinra is an interleukin-1 receptor antagonist
- Commonly used in paediatric disorders with hyperinflammation
- Anakinra will be a third option in the second randomisation **for children** >1 year old with PIMS-TS
- Second randomisation for children will become 2:2:1 randomisation
  - Tocilizumab *vs* Anakinra *vs* usual care alone

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TRIAL PROCEDURES

Review of amendments

- HRA has decided that RECOVERY amendments may be implemented **3 days** after full HRA approval given

- We recognise this is much shorter than standard 35 days but RECOVERY must take priority in R&D review process

- Some sites have tried to not implement amendments but this creates significant risk as IT system is centralised.

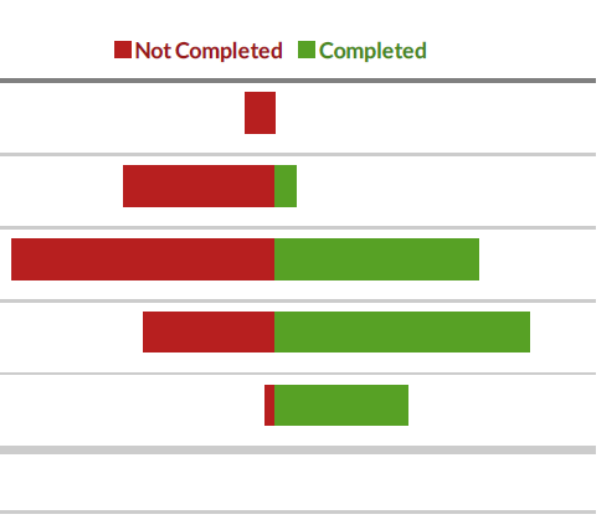
Completeness of follow-up

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

- NB 72h antibody safety forms are <u>no longer required</u>

Follow-up form completion summary

Days Since Rand.	FU Not Completed	FU Completed	Total Rands.
7 ≤ 14	3 (100.0%)	0 (0.0%)	3
14 ≤ 21	15 (88.2%)	2 (11.8%)	17
21 ≤ 28	26 (56.5%)	20 (43.5%)	46
28 ≤ 35	13 (34.2%)	25 (65.8%)	38
> 35	1 (7.1%)	13 (92.9%)	14
Total	**58 (49.2%)**	**60 (50.8%)**	**118**



Carry on recruiting!

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- 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
- We recognise challenge that current situation in the NHS presents and remain extremely grateful for your support, so THANK YOU!

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting for Pregnancy

25 January 2021

RECOVERY for pregnant women

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

Covid-19 and pregnancy

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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

BMJ: first published as 10.1136/bmj.m2107 on 8 June 2020.

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

AJOG American Journal of Obstetrics & Gynecology

ORIGINAL RESEARCH: OBSTETRICS | ARTICLES IN PRESS

Pregnant women with severe or critical COVID-19 have increased composite morbidity compared to non-pregnant matched controls

Chelsea A. DeBolt, MD • Angela Bianco, MD • Meghana A. Limaye, MD • ... Elianna Kaplowitz, MPH • Jessica R. Overbey, MS, DrPH • Joanne Stone, MD, MS • Show all authors

Published: November 19, 2020 • DOI: https://doi.org/10.1016/j.ajog.2020.11.022

RESEARCH

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 Coomar,[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

BMJ: first published as 10.1136/bmj.m33

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, MPH[1]; Romeo R. Galang, MD[1]; Titilope Oduyebo, MD[1]; Van T. Tong, MPH[1]; Kate R. Woodworth, MD[1]; John F. Nahabedian III, MS[1]; Eduardo Azziz-Baumgartner, MD[1]; Suzanne M. Gilboa, PhD[1]; Dana Meaney-Delman, MD[1]; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team

EDITORIALS

Check for updates

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 Chappell[4]

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2 Institute of Applied Health Research, University of Birmingham, Birmingham, UK
3 UK Obstetric Surveillance System Steering Committee, National Perinatal Epidemiology Unit, Oxford, UK
4 School of Life Course Sciences, King's College London, London, London, UK

Correspondence to: L C Chappell
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Cite this as: BMJ 2020;370:m3305
https://dx.doi.org/10.1136/bmj.m3305
Published: 25 August 2020

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.

BMJ: first published as 10.1136/bmj.m3305 on 25

Pregnant women – moderate risk group

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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

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- Covid-19 affects pregnant women
- Additional risk factors have been identified (ethnic minority groups, increasing gestation, higher maternal age, high BMI, pre-existing comorbidities)
- Some ongoing uncertainty over magnitude of increased risk (including with recent variant)

- Pregnant and postnatal women need evidence-based treatments
- Pregnant and postnatal women should be actively included in research
- RECOVERY trial has changed clinical practice, including for pregnant women

Covid-19 and pregnancy: RCOG

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THE ROYAL COLLEGE OF MIDWIVES

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

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HOME FOR PATIENTS FOR SITE STAFF RESULTS NEWS Search

For Site Staff / site teams

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 - dexamethasone (now only recruiting children)

RECOVERY intervention sheet - azithromycin

RECOVERY intervention sheet - tocilizumab

RECOVERY intervention sheet - assessing patients

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.

4 January 2021

5 January 2021

7 December 2020

8 December 2020

16 November 2020

17 November 2020

26 October 2020

27 October 2020

5 October 2020

6 October 2020

3 & 4 August 2020

14 & 15 September 2020

Pregnancy information document

RECOVERY
Randomised Evaluation of COVID-19 Therapy

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	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
Interventions	**First randomisation part A** • Colchicine **First randomisation part B** • Convalescent plasma • Synthetic neutralising antibodies **First randomisation part C** • Aspirin **Second randomisation** • Tocilizumab	Same interventions *(with exception of colchicine for pregnant and breastfeeding women - do not undertake part A randomisation for pregnant women)* **Pregnant and breastfeeding women are eligible for all other treatments shown.**
Follow-up/ outcomes	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 addition of UKOSS COVID-19 case number (for pregnancy and baby information) to allow later data linkage

Eligibility = same

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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[1] 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…

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- 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

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Current design

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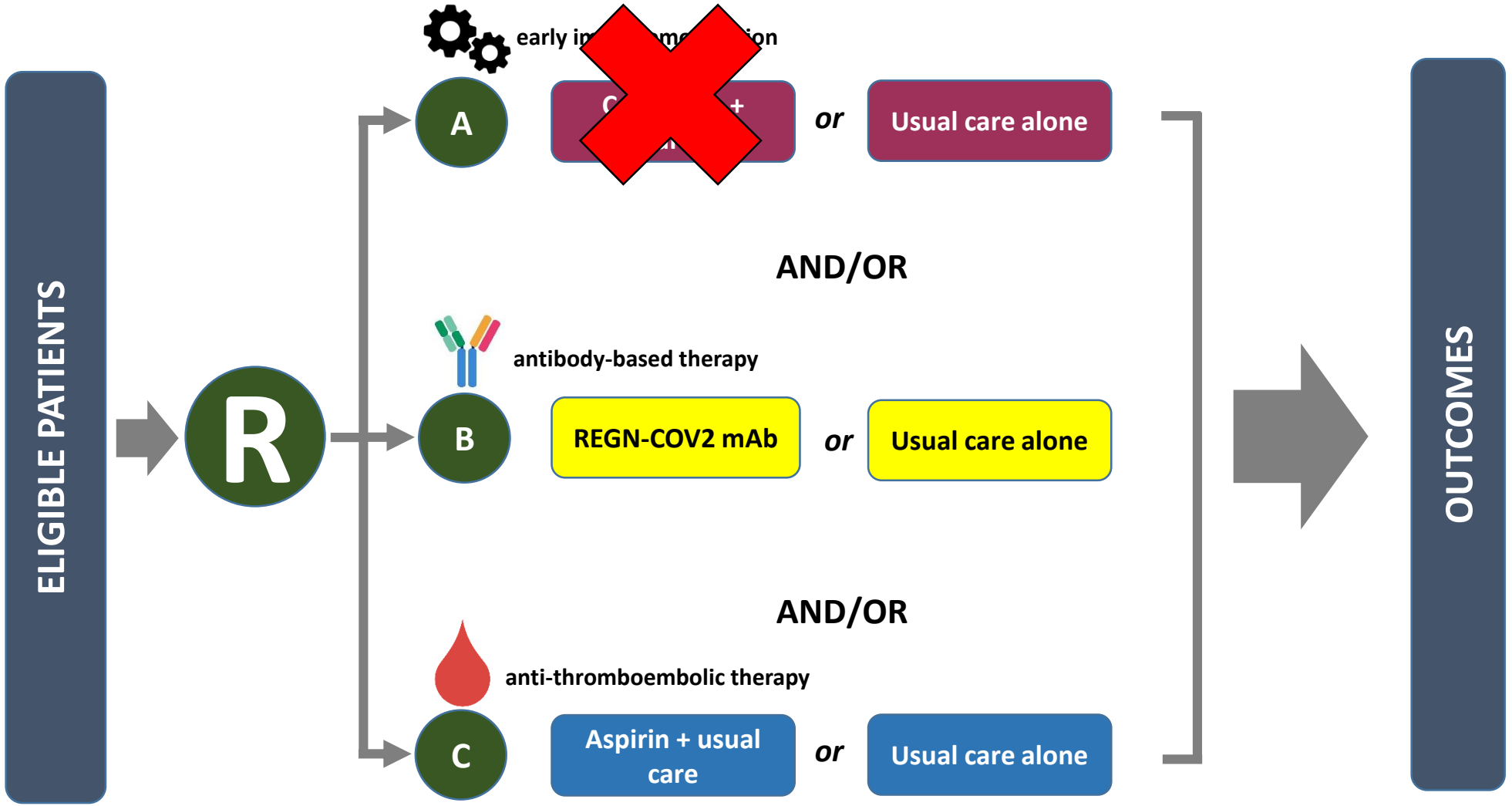

No colchicine allocation

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Colchicine

This is not currently recommended for inclusion in the RECOVERY trial for pregnant or breastfeeding women.

The RECOVERY trial is excluding women aged less than 55 years old, but older women (aged 55 years and older) who might be pregnant should also not have colchicine included in their randomisation. Colchicine is a drug used to treat gout (not commonly seen in women of reproductive age) and familial Mediterranean fever (which is seen in pregnant women). A systematic review of colchicine use for pregnant women with familial Mediterranean fever has reported no increased risk of adverse pregnancy outcomes,[1] and this is reflected in the UKTIS information on colchicine:
https://www.medicinesinpregnancy.org/bumps/monographs/MEDICATIONS-USED-TO-TREAT-COVID-19-IN-PREGNANCY/

However, there are theoretical concerns over use in pregnancy, as colchicine has anti-mitotic properties with evidence of teratogenicity in animals, and the BNF advises against its use in pregnancy:
https://bnf.nice.org.uk/drug/colchicine.html#pregnancy.

In light of the uncertainty, we are not recommending colchicine for use in pregnant women (or those of reproductive age), but if a pregnant woman is unintentionally exposed to the drug, then the usual pathway should be followed (e.g. referral to a Fetal Medicine Unit and/ or discussion with the UK Teratology Information Service for advice).

Next design (adults)

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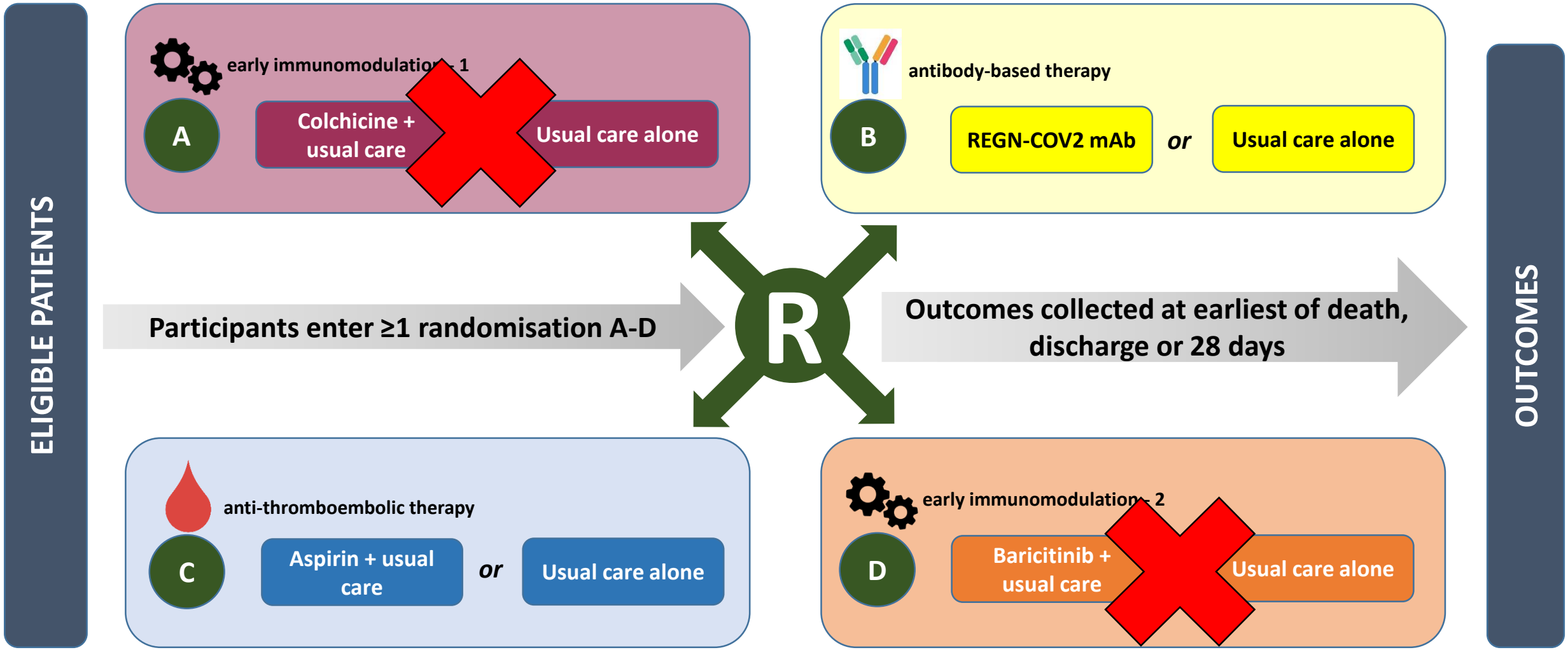

Follow-up = the same, + linkage

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NPEU

Nuffield Department of
POPULATION HEALTH

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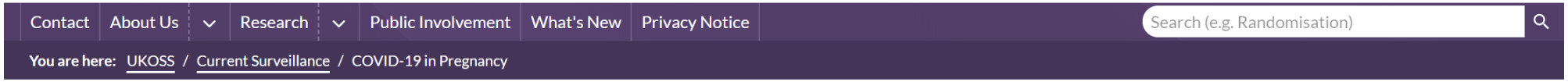

COVID-19 in Pregnancy

UKOSS
UK Obstetric Surveillance System

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

Update on progress

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Randomised Evaluation of COVID-19 Therapy

- 160 pregnancy leads identified, supported by research midwives
- Midwife champions on board

- 92 antenatal women recruited
- ≈20 (or more) postpartum women

Update from UKOSS this week

Nuffield Department of POPULATION HEALTH
Medical Sciences Division
UNIVERSITY OF OXFORD

UKOSS
UK Obstetric Surveillance System

Notifications by week

ICNARC data (critical care)

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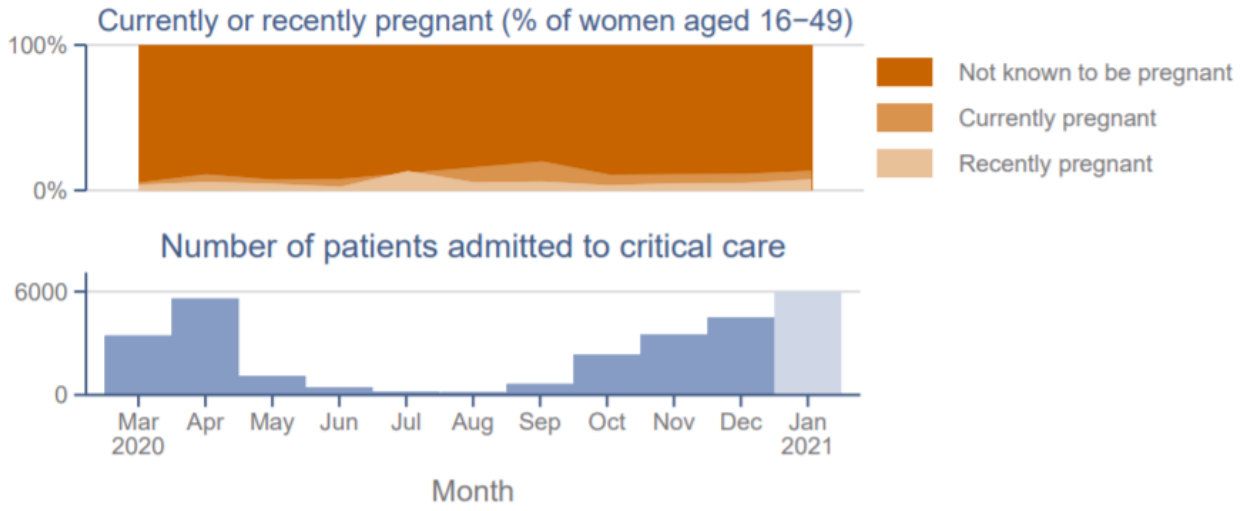
ICNARC report on COVID-19 in critical care:

England, Wales and Northern Ireland

22 January 2021



Medical history	Patients with confirmed COVID-19	
	Admitted from 1 Sep (N=17,015)	Admitted up to 31 Aug (N=10,938)
Currently or recently pregnant, n (% of females aged 16-49) [N=1398]		
Currently pregnant	92 (6.6)	29 (3.7)
Recently pregnant (within 6 weeks)	82 (5.9)	41 (5.2)
Not known to be pregnant	1224 (87.6)	720 (91.1)

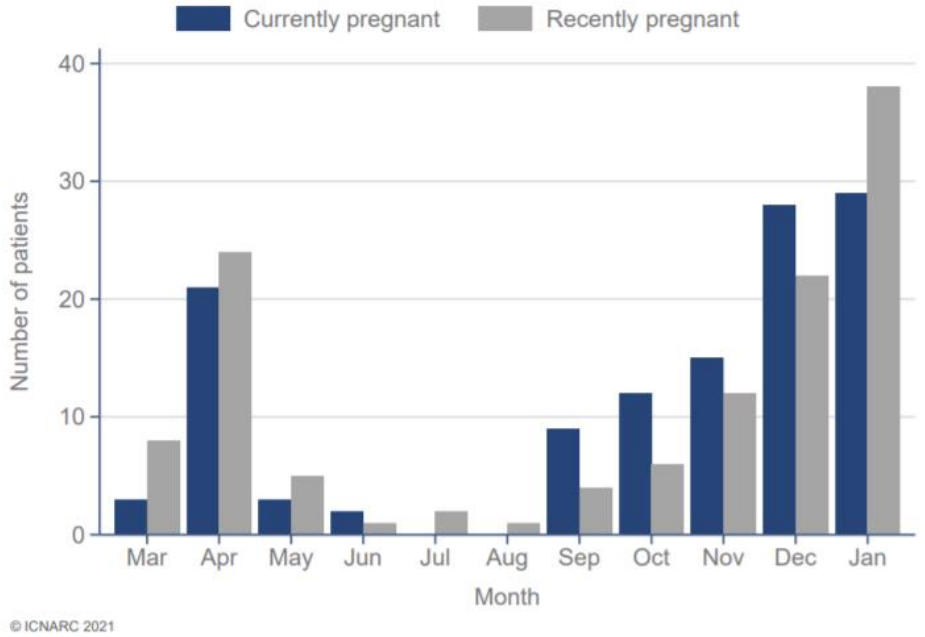


Figure 35. Numbers currently and recently pregnant

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

Next steps

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- Anticipate ongoing new cases over coming weeks
- Re-check teams are ready for recruitment
- Use these slides (on website) to update maternity teams
- Talk to physicians and main RECOVERY research teamsin main hospital providing care for pregnant women
- Think through pathways for notification of cases
- Use UKOSS as prompt to help (and for outcomes)
- Embed into usual practice
- Offer trial

Covid vaccine coming in 2021…

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Royal College of Obstetricians & Gynaecologists

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Coronavirus (COVID-19) infection and pregnancy

Coronavirus infection and pregnancy

Information for pregnant women and their families

These Q&As were updated on 12 January 2021 and relate to the Coronavirus (COVID-19) infection and pregnancy – guidance for healthcare professionals: Version 12 – 14 October 2020 published by the Royal College of Obstetricians and Gynaecologists, Royal College of Midwives and Royal College of Paediatrics and Child Health, with input from the Royal College of Anaesthetists, the Obstetric Anaesthetists' Association, Public Health England and Public Health Scotland.

Read our news stories relating to this guidance. More information on pregnancy and coronavirus, including leaflets you can print, are available from the NHS website.

But many pregnant women may not be offered the covid vaccine in the first 9 priority groups (JCVI list), so keep recruiting to RECOVERY for now.

1	Residents in a care home for older adults and their carers
2	All those 80 years of age and over Frontline health and social care workers
3	All those 75 years of age and over
4	All those 70 years of age and over Clinically extremely vulnerable individuals*
5	All those 65 years of age and over
6	All individuals aged 16 years** to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality***
7	All those 60 years of age and over
8	All those 55 years of age and over
9	All those 50 years of age and over

Q&A

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