Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting

4th & 5th January 2021

Agenda

RECOVERY
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1. Introductions
2. Update on progress
3. Tocilizumab
4. Colchicine
5. Convalescent plasma
6. Recent 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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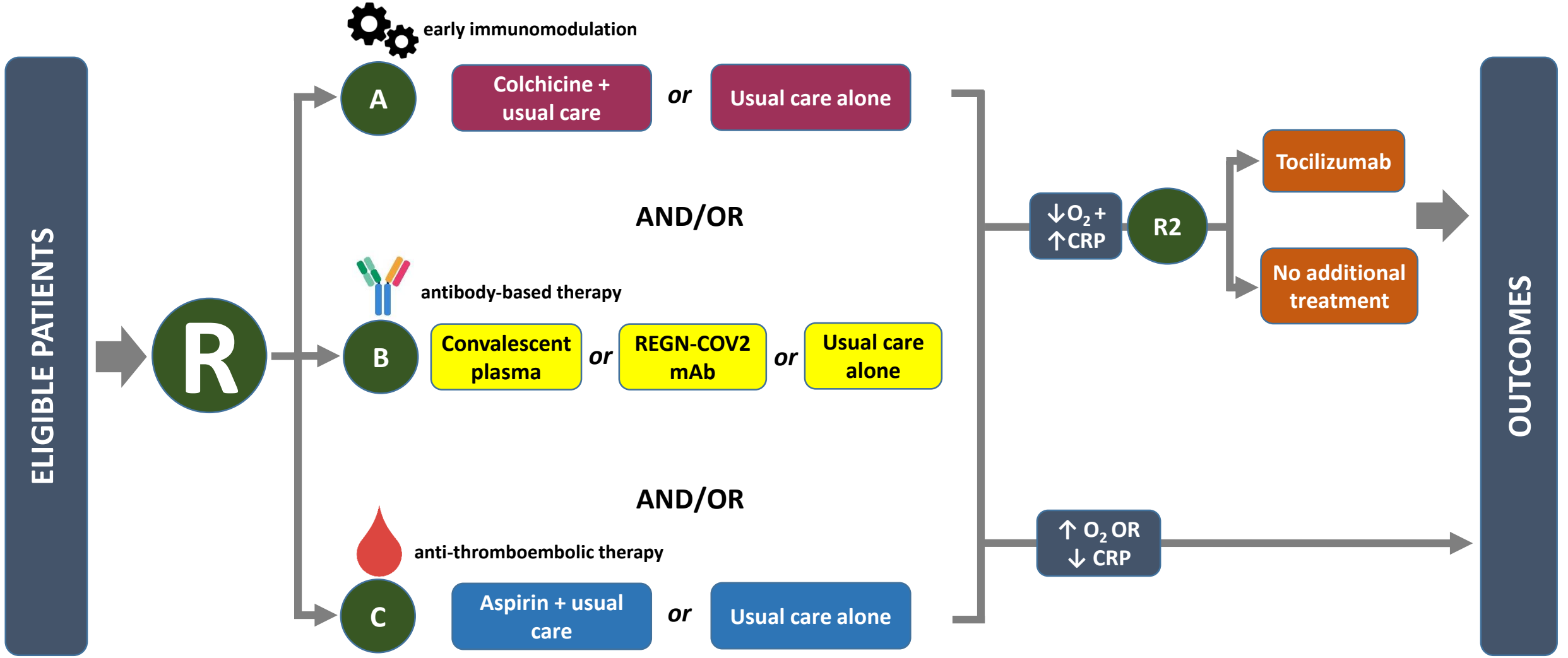

Recruitment by site and by time

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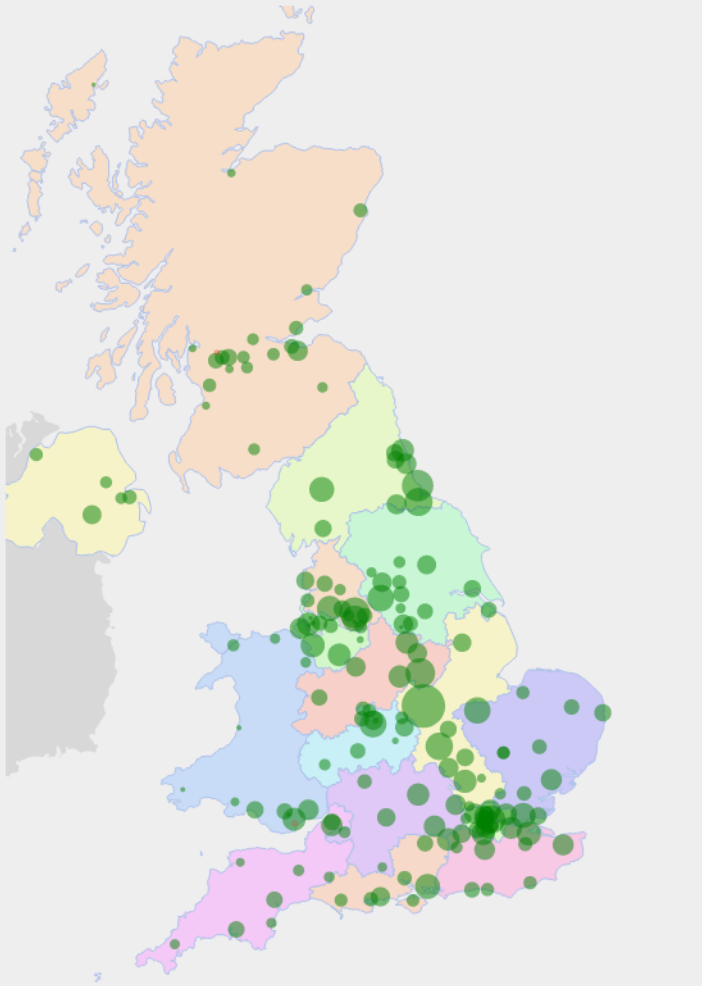
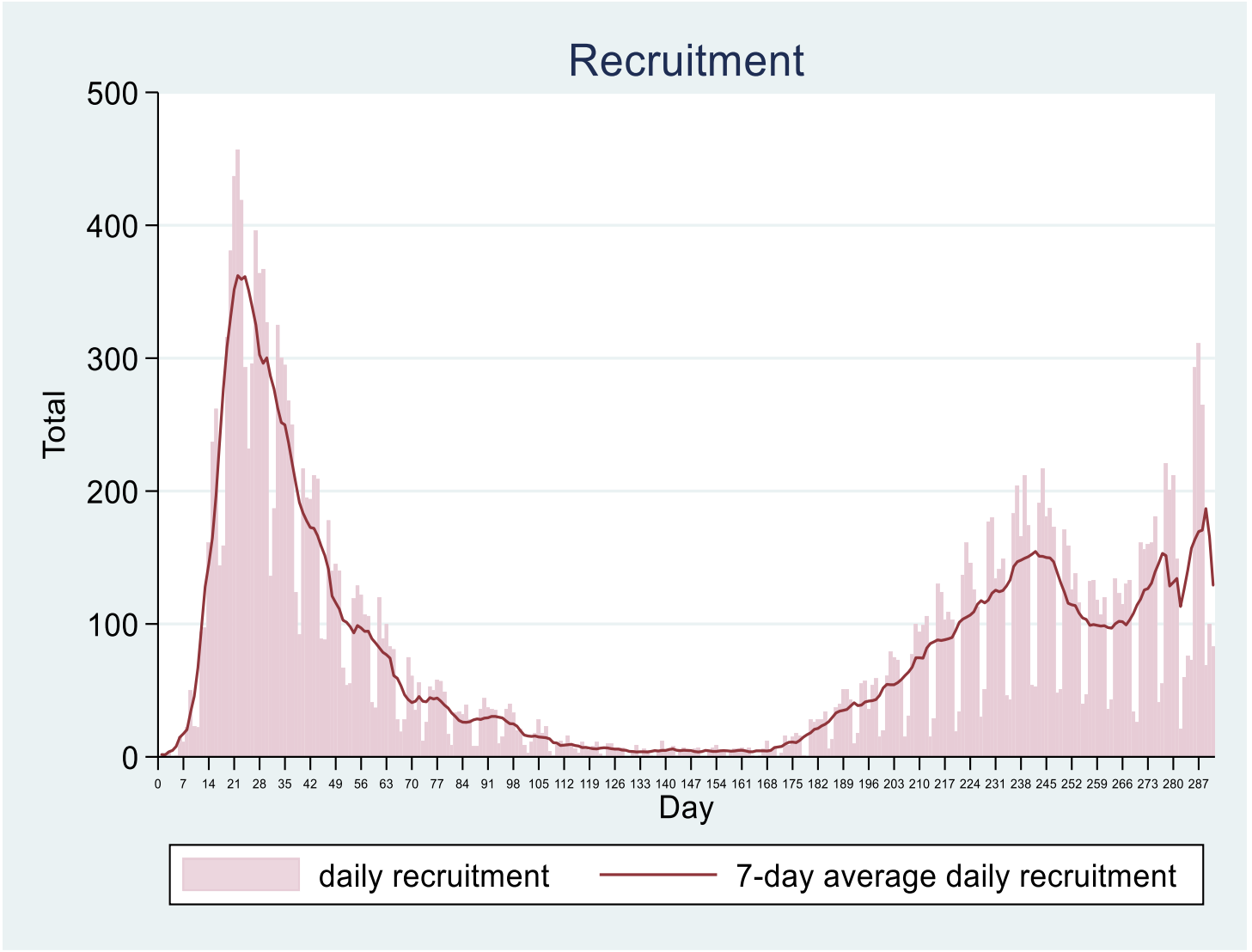
Active Sites	Recruiting Sites	Participants	Phase 2 rands.	Phase 3 rands.	Phase 4 rands.
176	174	23784	2700	10002	4478





Current numbers in comparisons

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- Colchicine *vs* usual care: ~2200
- Convalescent plasma *vs* usual care: ~8400
- REGN-COV2 *vs* usual care: ~2500
- Aspirin *vs* usual care: ~4300
- Tocilizumab *vs* usual care: ~2700

Recruitment

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- 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
- NIHR CRN has set a target of minimum 10% recruitment by each CRN
- Please let us know how we could support recruitment at your site

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TOCILIZUMAB

Tocilizumab in RECOVERY

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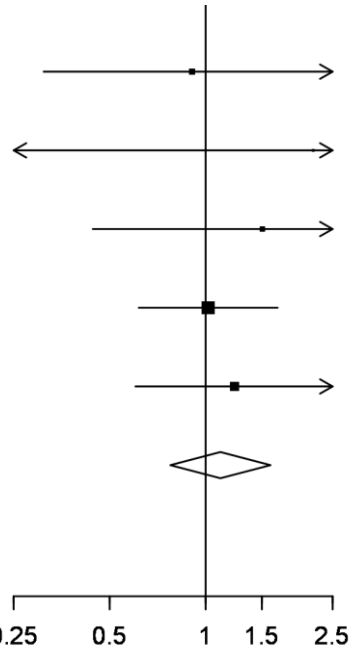
Trial	Events/Participants (%) Tocilizumab	Usual care	Odds Ratio (95% CI)
CORIMUNO-TOCI	7/64 (11%)	8/67 (12%)	0.91 (0.31-2.65)
RCT-TCZ-COVID-19*	2/60 (3%)	1/66 (2%)	2.17 (0.22-21.33)
BACC Bay	9/161 (6%)	3/82 (4%)	1.51 (0.44-5.13)
COVACTA	58/294 (20%)	28/144 (19%)	1.02 (0.62-1.68)
EMPACTA	26/249 (10%)	11/128 (9%)	1.23 (0.60-2.52)
Overall	**102/828 (12%)**	**51/487 (10%)**	**1.11 (0.77-1.60) p=0.56**



Tocilizumab in RECOVERY

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- REMAP-CAP preliminary results are encouraging, but unknown whether tocilizumab reduces mortality

- RECOVERY can provide a clear answer to this question, but recruitment must continue

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CONVALESCENT PLASMA

Convalescent plasma

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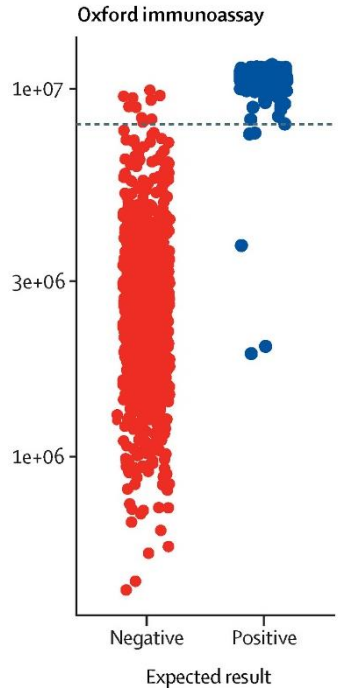
- Over 5500 participants in this comparison now
- Recent ‘negative’ trial from Argentina only included 300 participants
- Baseline serum samples now being analysed using Oxford immunoassay
  - Cut-off at 8 million for diagnosis



Antibody levels from first 3668 participants

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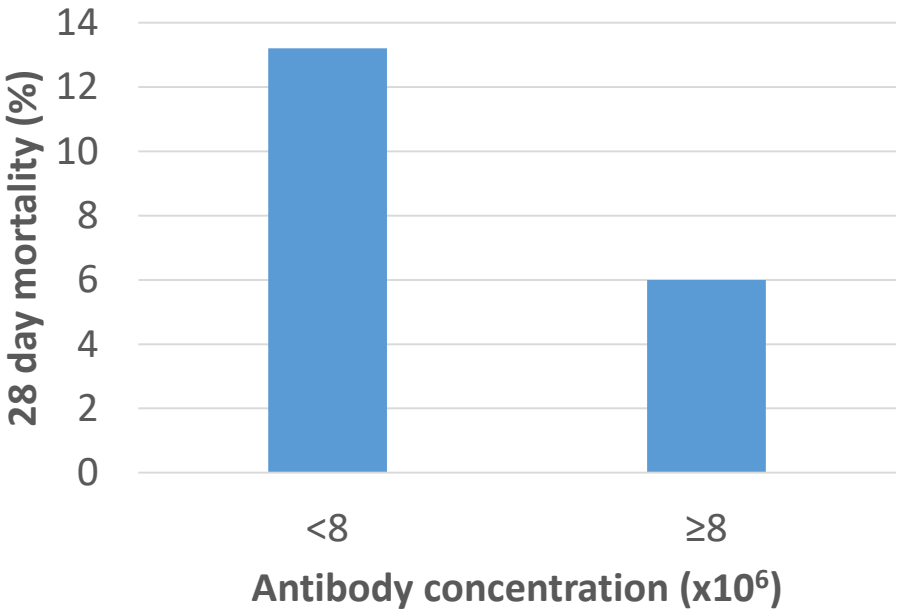
Baseline antibody level and risk of death



Baseline antibody level by arm

Recipient concentration	Convalescent plasma	Usual care
Available	73%	66%
Missing	27%	34%

Serum samples

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- **All** participants entering antibody comparison (CP vs mAb vs control) 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**

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RECENT TRIAL RESULTS

Baricitinib in COVID-19

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- Exaggerated immune response is a well-recognised part of the COVID-19 syndrome among people requiring hospitalisation

- Significant interest in treatments that modulate this response

- Recent genetic data from GenoMICC study suggest some inflammatory pathways are strongly linked to severe disease
  - e.g. people with more active *TYK2* are at higher risk of severe disease

Baricitinib in COVID-19

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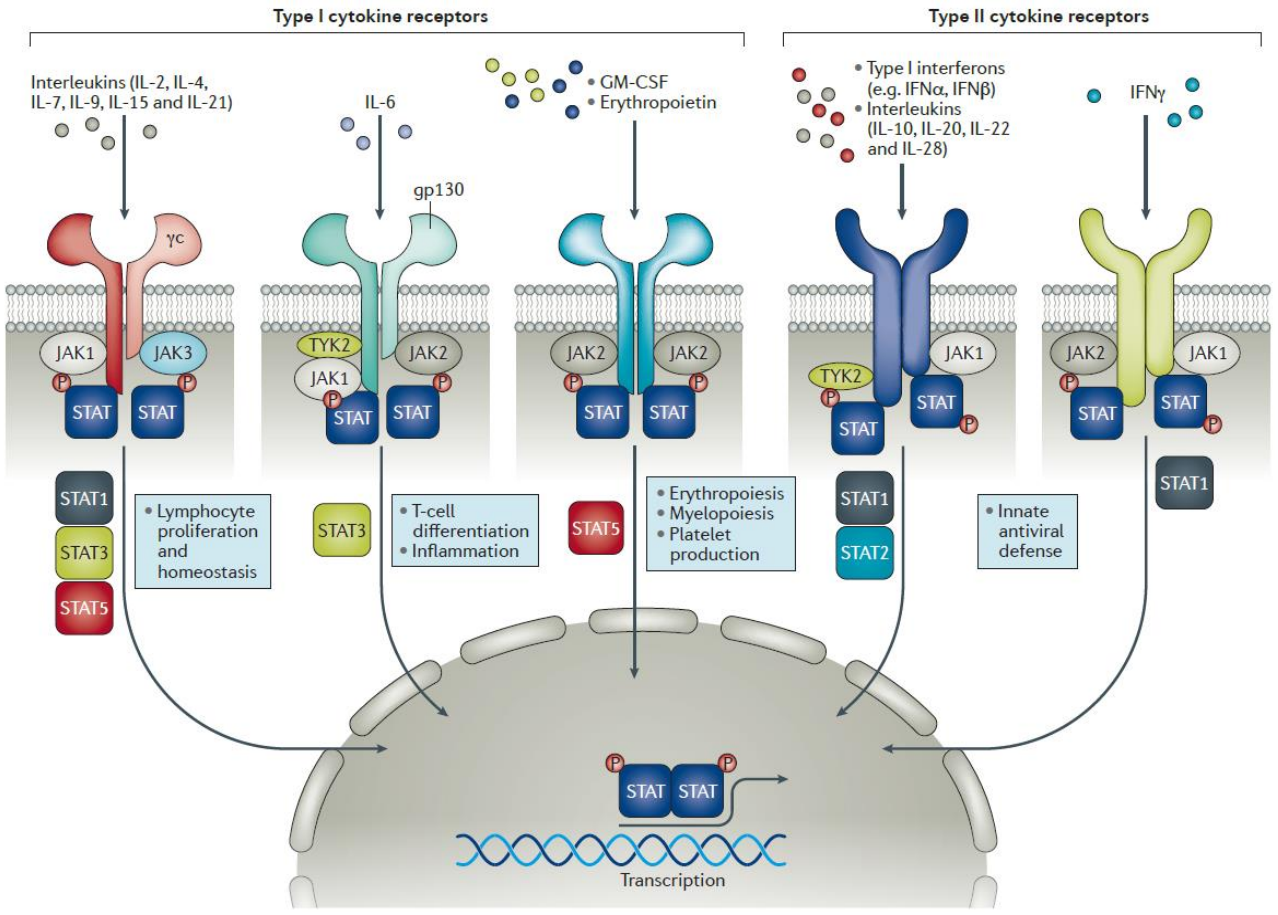
- *TYK2* encodes a protein called tyrosine kinase 2 which is one part of an intracellular signalling pathway common to many cytokines

- JAK proteins are in same family and work with STAT proteins to transmit signals from outside the cell to the nucleus and hence gene transcription

- Therefore inhibiting JAK/TYK2 might helpfully modify the immune response



ACTT-2 trial

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- 1033 participants hospitalised with COVID-19
- Randomly allocated to either:
  - Baricitinib plus remdesivir; or
  - Placebo plus remdesivir
- Primary outcome = time to recovery

ACTT-2 participants

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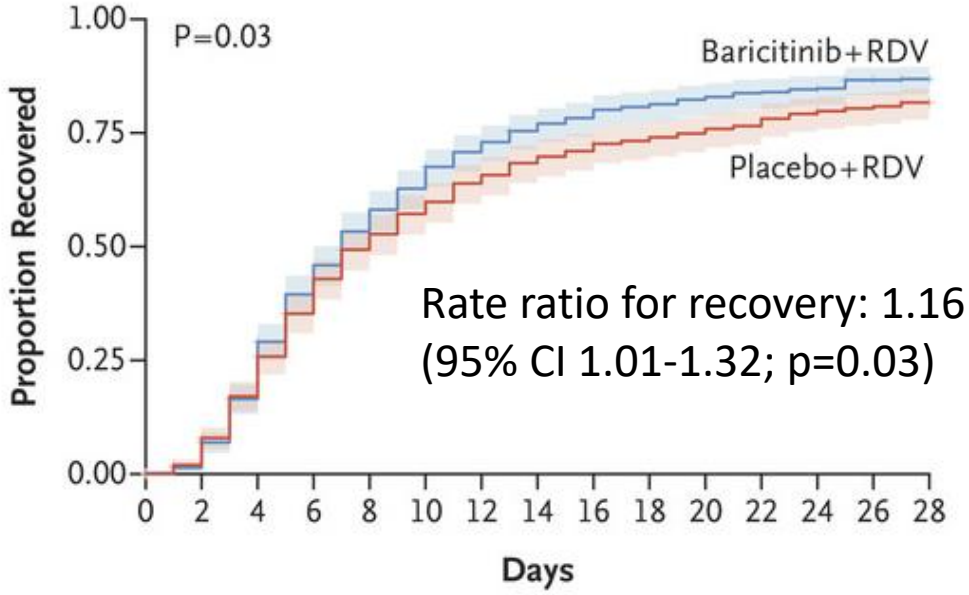
- Mean age 55 years old
- 63% men
- Recruited 8 days after symptoms started
- 32% on non-invasive or invasive ventilation

ACTT-2 results



Rate ratio for recovery: 1.16
(95% CI 1.01-1.32; p=0.03)

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)

Implications for RECOVERY

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- Genetic data and data from ACTT-2 both support baricitinib as a potential treatment for COVID-19
- Larger outcomes trial now required
- Baricitinib is undergoing detailed review by CTAP

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FUTURE AMENDMENTS TO THE PROTOCOL

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

Anakinra in RECOVERY

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- Dose = 2 mg/kg per day for 7 days

- **Contraindications:**
  - Neutrophils <1.5 x10^9/L
  - Pregnancy*
  - No drug-drug interactions

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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.

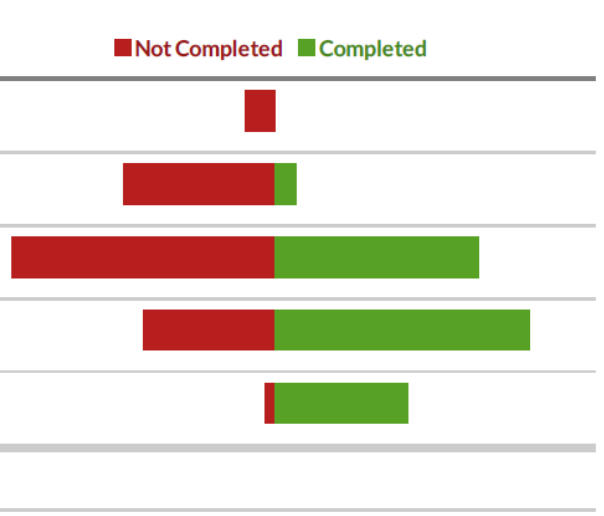
Completeness of follow-up

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

- Please do complete these as soon as possible

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

4 January 2021

RECOVERY for pregnant women

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Randomised Evaluation of COVID-19 Therapy

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

Published 19 December 2020
Last updated 31 December 2020 — see all updates
From: Department of Health and Social Care

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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

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Headline messages:

- Covid-19 affects pregnant women
- Additional risk factors have been identified (ethnic minority groups, increasing gestation, higher maternal age, high body mass index, pre-existing comorbidities)
- 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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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 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.

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**
13 July 2020	**14 July 2020**
29 June 2020	**30 June 2020**
15 June 2020	**16 June 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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Design for pregnant women

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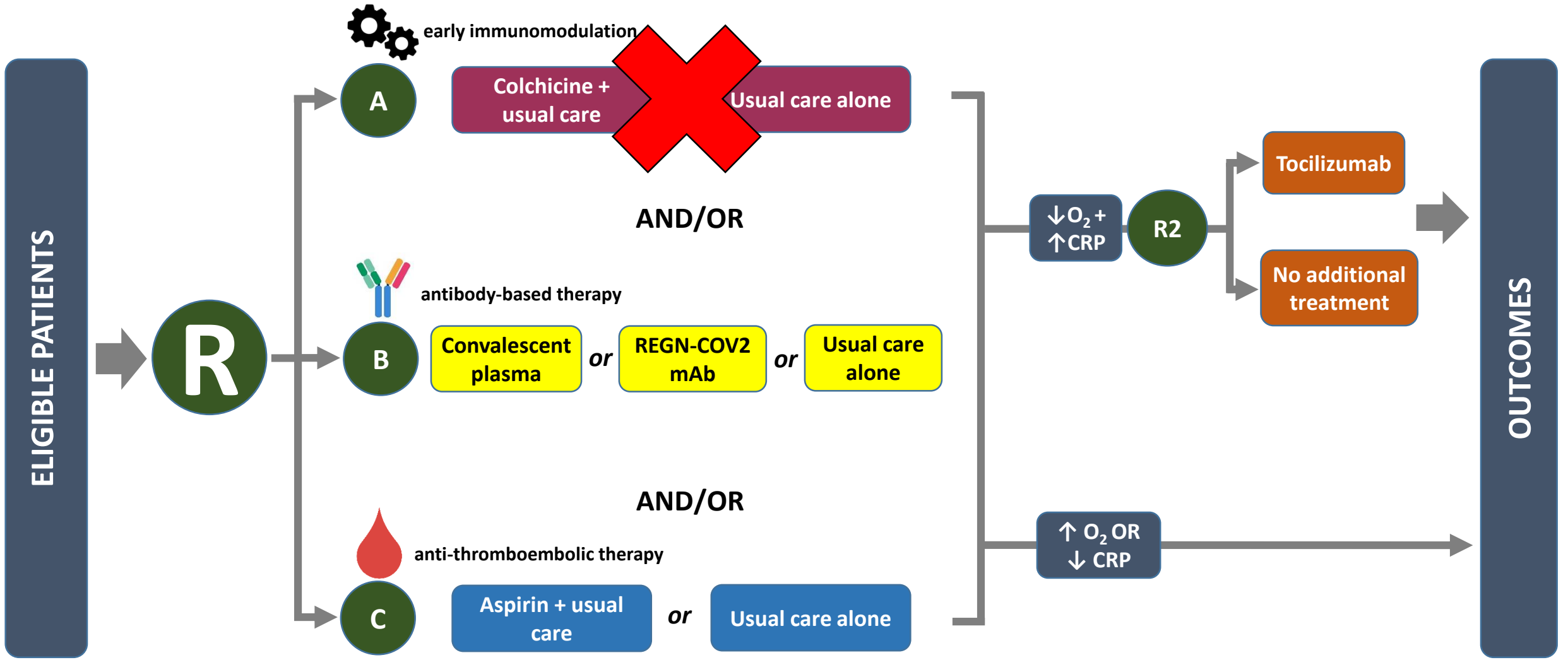

No colchicine allocation

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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).

Follow-up = the same, + linkage

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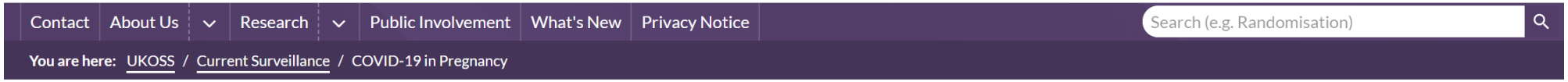
NPEU

Nuffield Department of
POPULATION HEALTH

UNIVERSITY OF OXFORD



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

RECOVERY
Randomised Evaluation of COVID-19 Therapy

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

- 56 antenatal women recruited
- ≈14 more postpartum women (to Sept 2020)

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

31 December 2020

Table 2. Patient characteristics: medical history

Medical history	Patients with confirmed COVID-19	
	Admitted from 1 Sep (N=10,149)	Admitted up to 31 Aug (N=10,935)
Currently or recently pregnant, n (% of females aged 16-49) [N=791]		
Currently pregnant	56 (7.1)	29 (3.7)
Recently pregnant (within 6 weeks)	39 (4.9)	41 (5.2)
Not known to be pregnant	696 (88.0)	720 (91.1)

Next steps

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- Anticipate ongoing new cases over coming weeks
- Check teams are ready for recruitment
- Use these slides (on website) to update maternity teams
- 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

Covid vaccine coming in 2021…

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Royal College of Obstetricians & Gynaecologists

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Updated advice on COVID-19 vaccination in pregnancy and women who are breastfeeding

News **30 December 2020**

The Government has today accepted the recommendation from the Medicines and Healthcare products Regulatory Agency (MHRA) to authorise Oxford University/AstraZeneca's COVID-19 vaccine for use. The Joint Committee on Vaccination and Immunisation (JCVI) has also published its latest advice for the priority groups to receive the Oxford University/AstraZeneca and the Pfizer/BioNTech vaccines. This includes updated advice for pregnant and breastfeeding women who meet other criteria for priority vaccination.

The JCVI confirms that although the available data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy.

But most pregnant women will <u>not</u> 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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