Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting

5th October 2020

Agenda

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1. Introductions
2. Update on progress
3. REGN-COV2
4. Other developments
5. Future plans
6. Pregnancy update
7. 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

New trial design

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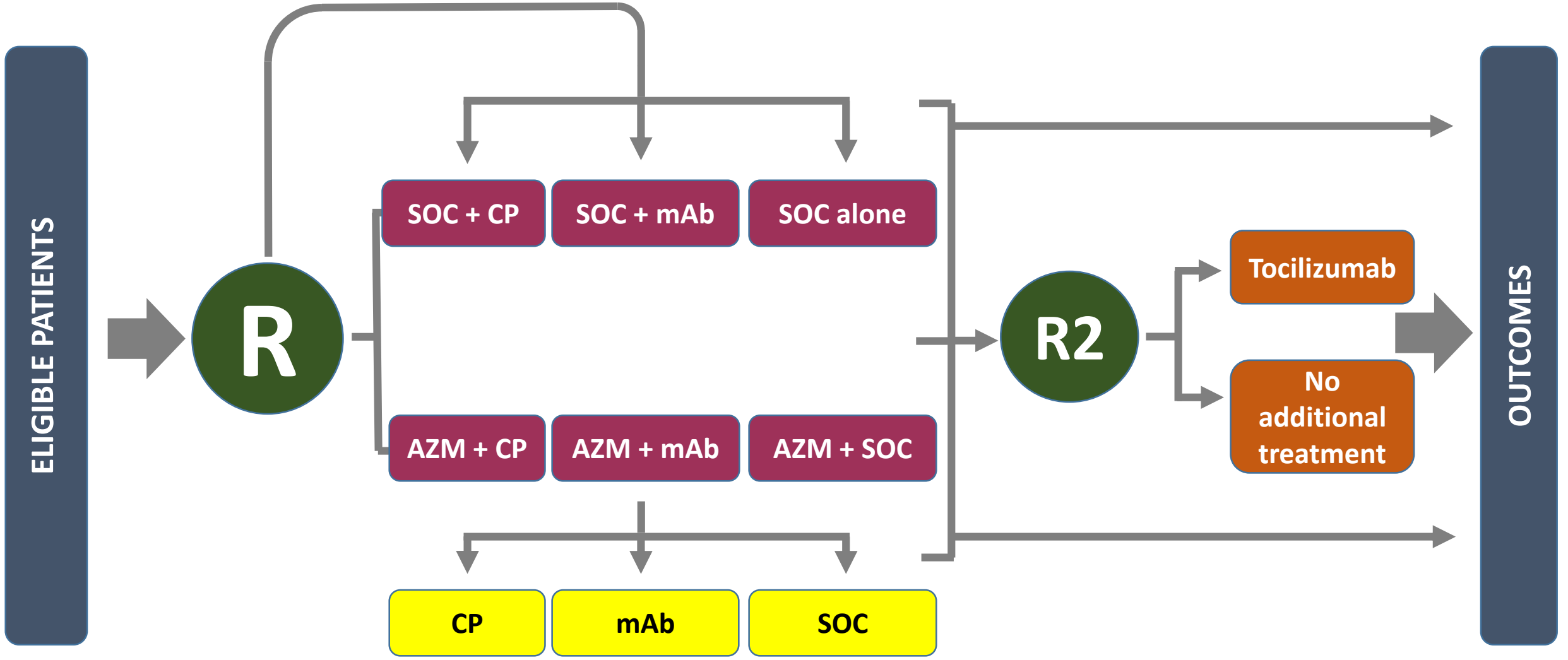

Recruitment by site and by time

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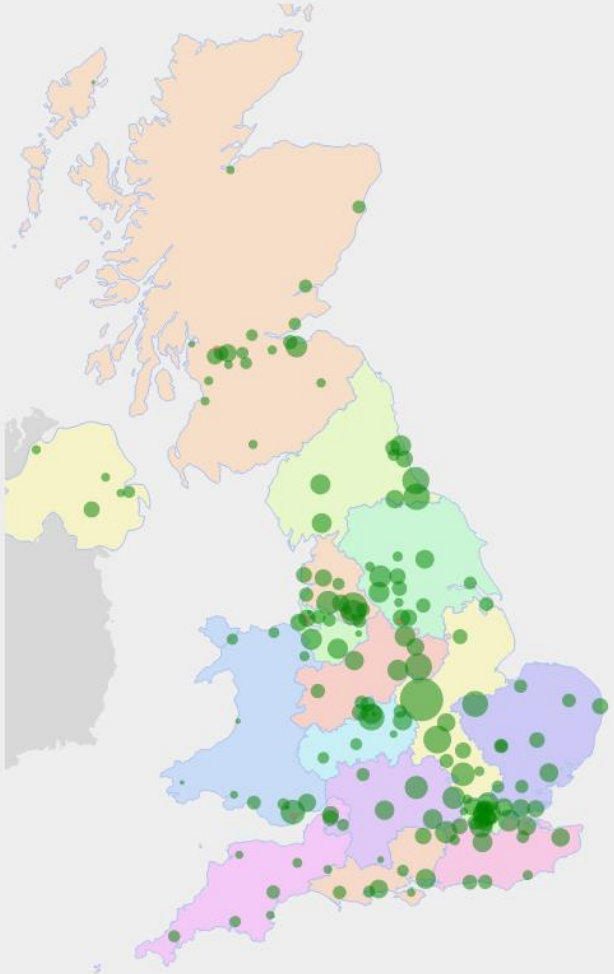
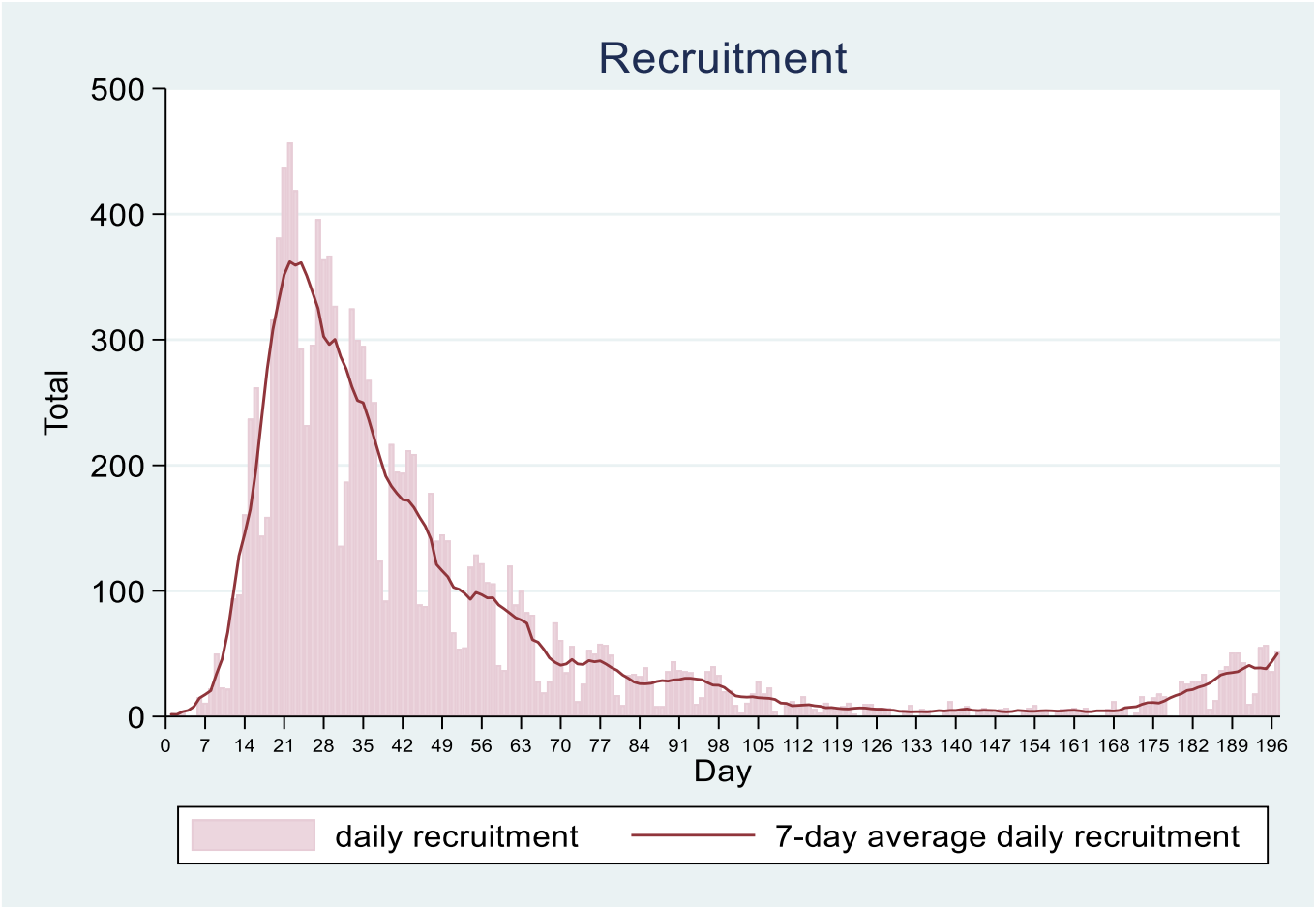
Active Sites	Recruiting Sites	Participants	Phase 2 rands.	Phase 3 rands.
176	172	13068	1018	963





Recruitment

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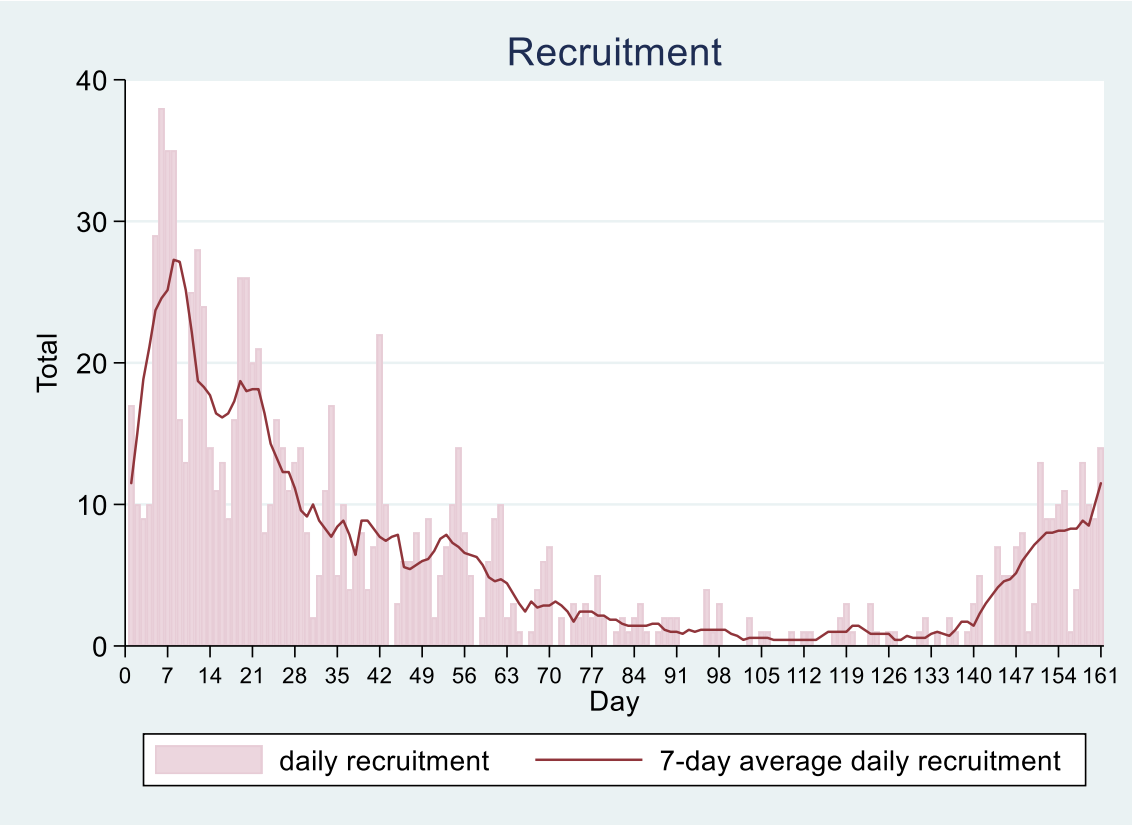
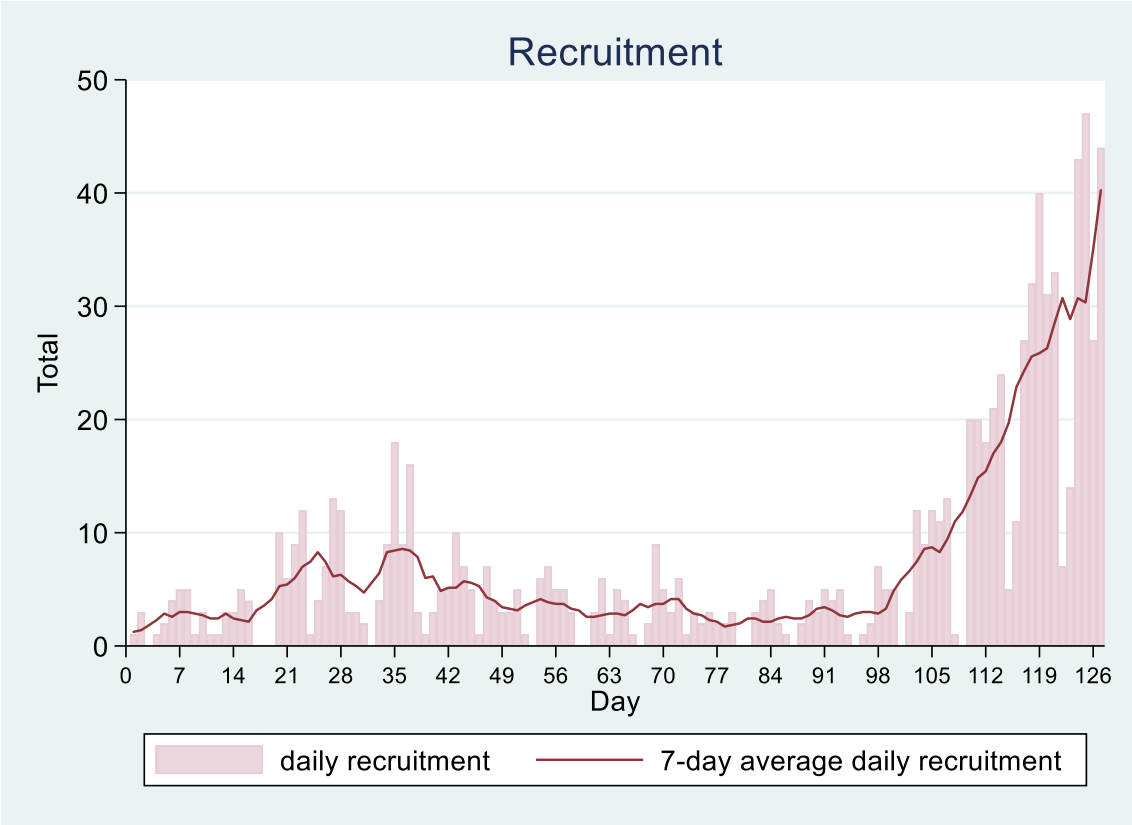
- Tocilizumab vs control



- Convalescent plasma vs control



Recruitment

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- Continued recruitment is essential

- 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

- Please consider “re-launching” the trial at your site to refresh people and inform any new team members of how they can contribute

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REGN-COV2

REGN-COV2

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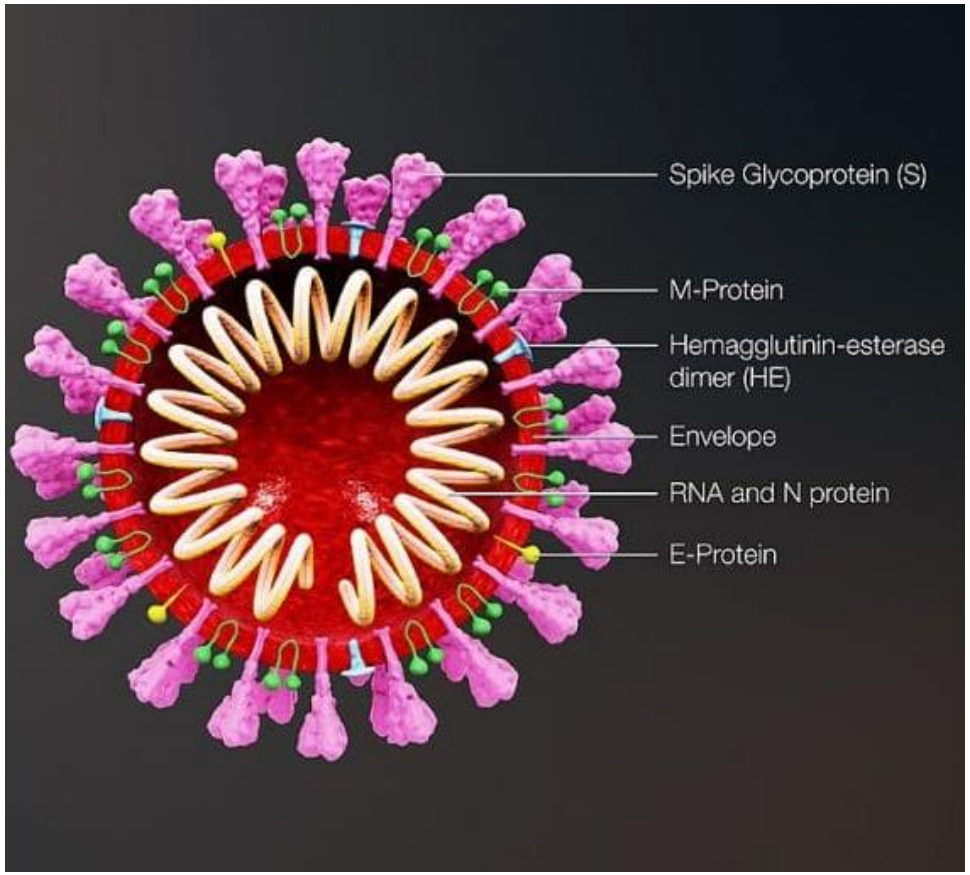
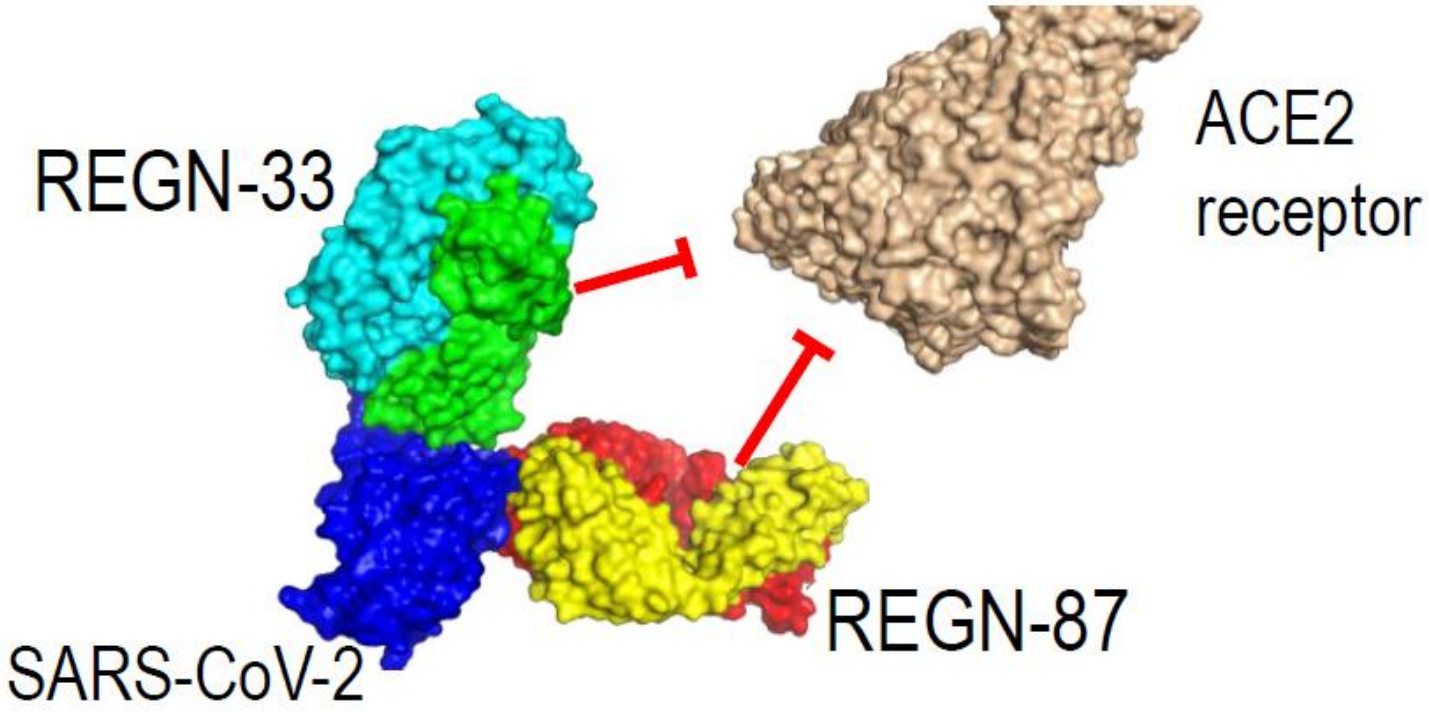
- Several companies are now producing monoclonal antibodies (mAbs) against SARS-CoV-2 “spike” protein





REGN-COV2

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- 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

Safety of REGN-COV2

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- REGN-COV2 mAb has been given to >1000 patients so far in early phase trials
  - No serious adverse reactions
  - Minor infusion reactions do occur during infusion

- Other trials ongoing in other clinical scenarios e.g. outpatient, prophylaxis
  - Preliminary results from outpatient trial suggest more rapid reduction in viral load and symptoms compared to placebo

It’s good enough for him…

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BBC | BBC Account | Home | News | Sport

Welcome to the BBC

LIVE Trump receives treatment as new cases emerge

REGN-COV2 site setup

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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 (V3.0 release today) and complete local risk assessment to determine where mAb will be prepared
   - Confirm staff details to RECOVERY team so user accounts on Cenduit websystem can be created (Cenduit user guide on website)
   - Indicate when they will be ready to:
     1. Receive drug
     2. Support allocation to a trial participant

REGN-COV2 dos and don’ts

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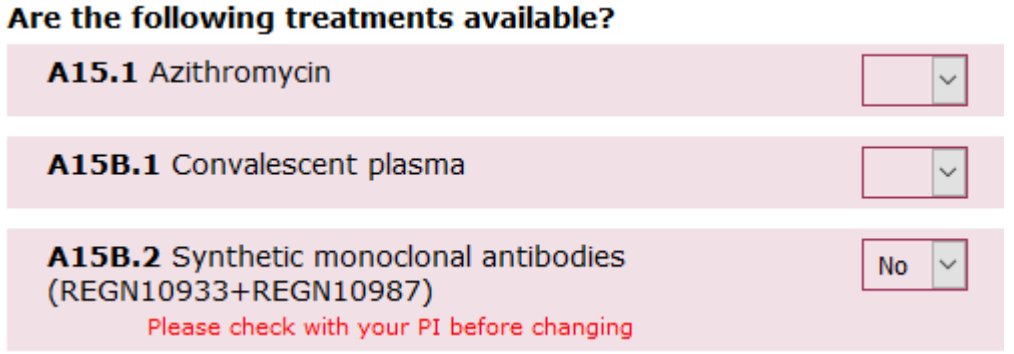
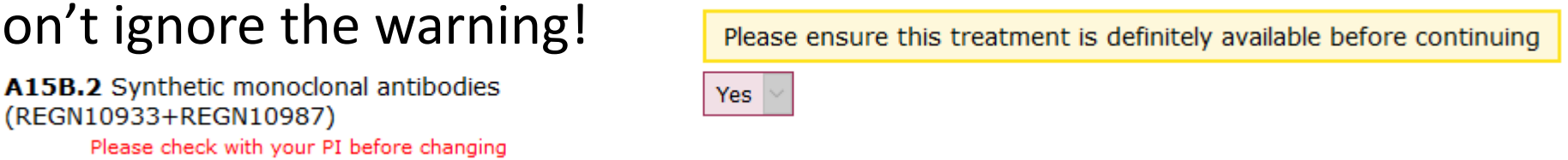
- Please **DO NOT** indicate REGN-COV2 is available if system suggests it is not *unless you are absolutely sure!*



- Please don’t ignore the warning!



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

When to include REGN-COV2

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- 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

Administration

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- REGN-COV2 is reconstituted in 250 mL bag of normal saline and infused over 60 minutes
- Does not necessarily require delivery by research staff
- Observations and beginning, middle and end (as for blood product)
- Infusion should be stopped if reaction occurs
  - Reaction should be treated symptomatically
  - If severe, infusion should be abandoned
  - Otherwise can be restarted at half the original rate on medical advice

Safety assessments

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- Any suspected serious adverse reactions should be reported according to protocol
- 72h safety form to be completed for all participants received REGN-COV2 (or in control arm)
- Standard 28 day follow-up form to be completed

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OTHER DEVELOPMENTS

Outside RECOVERY

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- EMPACTA trial of tocilizumab among adults with hypoxia not on mechanical ventilation
  - Primary outcome: mechanical ventilation or death by day 28
  - HR 0.56 (95% CI 0.32-0.97)

- PLACID trial of convalescent plasma among hospitalized adults with hypoxia
  - Primary outcome: severe hypoxia or death
  - OR 1.09 (95% CI 0.67-1.77)
  - >1/3 donors had undetectable anti-SARS-CoV-2 neutralising antibodies

Other developments in RECOVERY: Phase 2

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Department of Health & Social Care

Guidance

Guidance: making a proposal for COVID-19 therapeutics clinical trials

Published 17 August 2020

Contents

Introduction

Given the success of the Phase III RECOVERY platform in delivering a single platform trial across the NHS, the UK Government has increased investment in an expanded platform which will operate for the next 24 months. This will include new treatments tested in Phase II and Phase III studies which will now be delivered through the RECOVERY platform (RECOVERY+) in patients admitted to hospital.

New treatments can be proposed for inclusion in the RECOVERY+ platform for both Phase II and Phase III trials. They will be considered by the UK COVID-19 Therapeutics Advisory Panel (UK-CTAP).

Subcommittees that have met to date:

- Antiviral
- Anticoagulation
- Immunomodulation
- Renin-angiotensin system

Other developments: RECOVERY international

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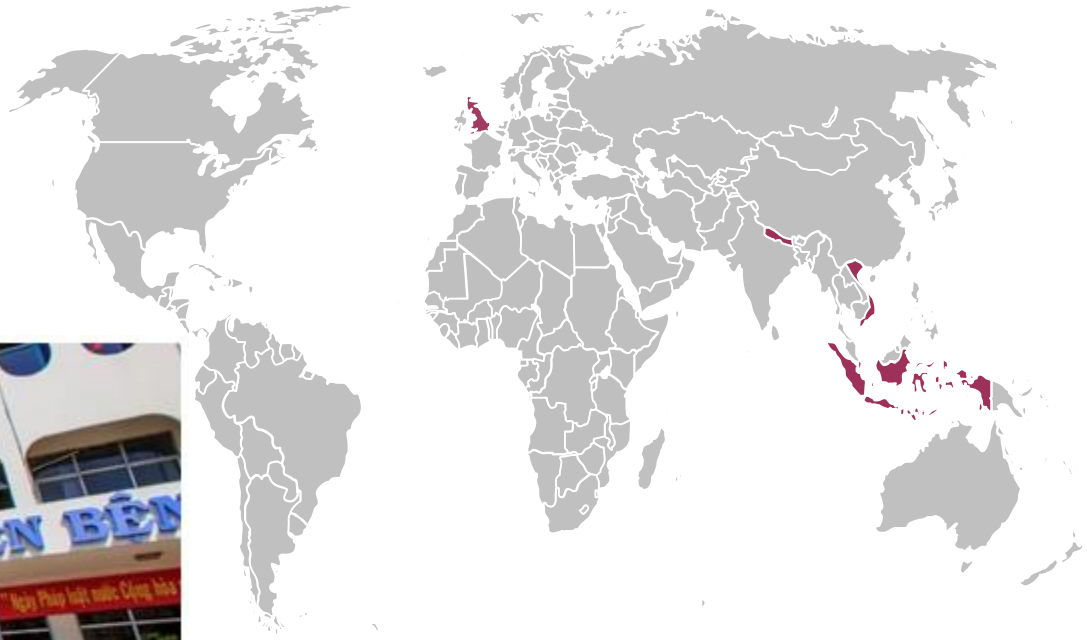
- RECOVERY has been approached by other countries asking to participate

- Discussions are progressing with Vietnam, Indonesia and Nepal



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

Pharmacogenomic substudy

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- Azithromycin known to prolong QT interval, but genetic determinants unknown

- Substudy for interested sites which requires:
  - ECG prior at baseline and 48h (uploaded to OpenClinica)
  - Co-enrolment into GenoMICC or ISARIC-4C encouraged (for genetic samples)

- Please e-mail recoverytrial@ndph.ox.ac.uk if interested

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TRIAL PROCEDURES

Serum samples

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- 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

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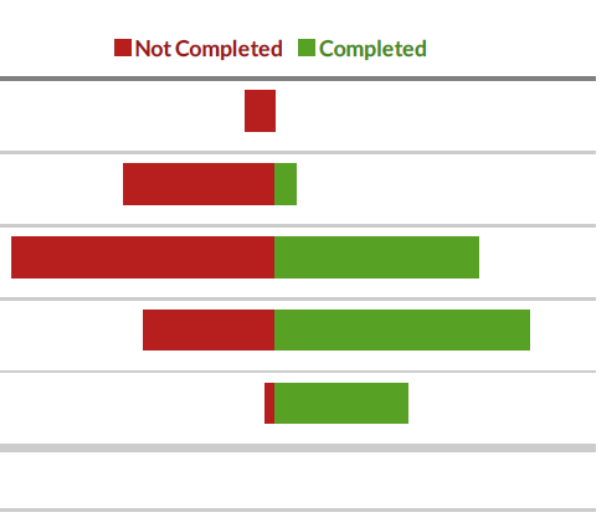
- Weekly reminders highlighting participants randomised >28 days ago without complete form **and also** those needing an Antibody Comparison 72h safety form

- 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 is expanding both in terms of therapies being tested and geography covered, so it is an exciting time for the trial.
- As admission rates rise, please ensure team are aware and prepared to recruit
- Need to continue recruitment and collection of follow-up information to provide DMC with information about efficacy and safety of study treatments
- Thank you for your support.

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting for Pregnancy

5 October 2020

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

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.

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Additional material is published online only. To view please visit the journal online.

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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, including transmission of infection, for mothers and infants.

DESIGN

Prospective national population based cohort study using the UK Obstetric Surveillance System (UKOSS).

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 the first 12 hours after birth.

CONCLUSIONS

Most pregnant women admitted to hospital with SARS-CoV-2 infection were in the late second or third trimester, supporting guidance for continued social distancing measures in later pregnancy. Most had good outcomes, and transmission of SARS-CoV-2 to

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

Covid-19 and pregnancy (UKOSS 2020)

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Characteristic	Estimated No of maternities	No of pregnant women admitted with SARS-CoV-2	Incidence per 1000 maternities	Rate ratio (95% CI)
Age*, years:				
<20	2532	4	1.6	0.4 (0.1 to 1.1)
20-34	63 768	248	3.9	1 (reference)
≥35	19 992	175	8.8	2.3 (1.8 to 2.7)
Body mass index†:				
Normal (<25)	36 377	126	3.5	1 (reference)
Overweight (25 to <30)	20 836	141	6.8	2.0 (1.5 to 2.5)
Obese (≥30)	16 154	140	8.7	2.5 (2.0 to 3.2)
Ethnic group (England only)‡:				
White	49 282	173	3.5	1 (reference)
Asian	7400	103	13.9	4.0 (3.1 to 5.1)
Black	3135	89	28.4	8.1 (6.2 to 10.5)
Chinese/other	2960	28	9.5	2.7 (1.7 to 4.0)
Mixed	1304	0	0.0	0.0 (0.0 to 3.8)

Covid-19 and pregnancy

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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

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Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ*2020;370:m3320
http://dx.doi.org/10.1136/bmj.m3320

Accepted: 23 August 2020

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 and meta-analysis.

DATA SOURCES

Medline, Embase, Cochrane database, WHO COVID-19 database, China National Knowledge Infrastructure (CNKI), and Wanfang databases from 1 December 2019 to 26 June 2020, along with preprint servers, social media, and reference lists.

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% to14%; 28 studies, 11 432 women) of pregnant and recently pregnant women attending or admitted to hospital for any reason were diagnosed as having suspected or confirmed covid-19. The most common clinical manifestations of covid-19 in pregnancy were fever (40%) and cough (39%). Compared with non-pregnant women of reproductive age, pregnant and recently pregnant women with covid-19 were less likely to report symptoms of fever (odds ratio 0.43, 95% confidence

Covid-19 and pregnancy (SR and MA)

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WHAT IS ALREADY KNOWN ON THIS TOPIC

Pregnant women are considered to be a high risk group for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, and the potential adverse effects of the virus on maternal and perinatal outcomes are of concern

In non-pregnant populations admitted to hospital with coronavirus disease 2019 (covid-19) the most common symptoms are fever, cough, and dyspnoea, reported in more than two thirds of individuals

Advancing age, high body mass index, non-white ethnicity, and pre-existing comorbidities are risk factors for severe covid-19 in the general population

WHAT THIS STUDY ADDS

Pregnant and recently pregnant women with covid-19 diagnosed in hospital are less likely to manifest symptoms of fever and myalgia than non-pregnant women of reproductive age and might be at increased risk of admission to an intensive care unit

Risk factors for severe covid-19 in pregnancy include increasing maternal age, high body mass index, and pre-existing comorbidities

Pregnant women with covid-19 are more likely to experience preterm birth and their neonates are more likely to be admitted to a neonatal unit

Covid-19 and pregnancy

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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

Covid-19 and pregnancy

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1. Key messages

New recommendations

1. 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. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/Royal Colleges of Physicians COVID-19 Guideline Development Groups]**
2. Ensure that pregnant and postpartum women are considered for antiviral or other specific therapies for COVID-19 as part of routine care, early access or compassionate use programmes. Pregnant and postpartum women should not be excluded from clinical trials unless there is a clear contraindication. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/ Royal Colleges of Physicians COVID-19 Guideline Development Groups]**
3. Provide specific advice to pregnant and post-partum women with COVID-19 infection about the risk of deterioration and when to seek urgent medical attention or go to the hospital.This should be communicated via an interpreter if necessary. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association COVID-19 Guideline Development Group]**
4. Ensure that communication with partners and families, including via an interpreting service if necessary, and facilitating visits between women and their partners is a priority when women are critically ill. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/ Royal Colleges of Physicians COVID-19 Guideline Development Groups]**
5. Establish triage processes to ensure that women with mental health concerns can be appropriately assessed, including face-to-face if necessary, and access specialist perinatal mental health services in the context of changes to the normal processes of care due to COVID-19. Perinatal mental health services are essential and face to face contact will be necessary in some circumstances. There is a clear role for involvement of the lead mental health obstetrician or midwife in triage and clinical review. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/Royal College of Psychiatrists COVID-19 Guideline Development Groups; Local Maternity Systems; Mental Health Service Providers; Health Boards]**
6. Ensure that referral with mental health concerns on more than one occasion is considered a 'red flag' which should prompt clinical review, irrespective of usual access thresholds or practice. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of Midwives/Obstetric Anaesthetists Association/ Royal College of Psychiatrists COVID-19 Guideline Development Groups; Local Maternity Systems; Mental Health Service Providers; Health Boards]**
7. Update guidance to reflect that safeguarding actions, including removal to a place of safety if necessary, should be followed in the context of public health measures such as lockdown. **[ACTION: Local Authorities, Adult Protection Committees, Northern Ireland Adult Safeguarding Partnership, Hospitals and Health Boards, Primary Care]**

Covid-19 and pregnancy

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1. 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. **[ACTION:**

2. Ensure that pregnant and postpartum women are considered for antiviral or other specific therapies for COVID-19 as part of routine care, early access or compassionate use programmes. Pregnant and postpartum women should not be excluded from clinical trials unless there is a clear contraindication. **[ACTION: Royal College**

3. Provide specific advice to pregnant and post-partum women with COVID-19 infection about the risk of deterioration and when to seek urgent medical attention or go to the hospital.This should be communicated via an interpreter if necessary. **[ACTION: Royal College of Obstetricians and Gynaecologists/Royal College of**

4. Ensure that communication with partners and families, including via an interpreting service if necessary, and facilitating visits between women and their partners is a priority when women are critically ill. **[ACTION: Royal**

Covid-19 and pregnancy

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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]

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.

Covid-19 and pregnancy

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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

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- Be aware of the interim government guidance based on the results of the RECOVERY trial, which states that steroid therapy should be considered for 10 days or to hospital discharge, whichever is sooner, for adults unwell with COVID-19 and requiring oxygen (in pregnant adults, use oral prednisolone 40 mg once a day or intravenous hydrocortisone 80 mg twice a day).

RECOVERY for pregnant women

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HOME FOR PATIENTS FOR SITE STAFF 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.

INTERVENTION INFORMATION

RECOVERY intervention sheet - lopinavir-ritonavir

RECOVERY intervention sheet - hydroxychloroquine

RECOVERY intervention sheet - dexamethasone

RECOVERY intervention sheet - azithromycin

RECOVERY intervention sheet - tocilizumab

GUIDES FOR SPECIFIC PATIENT GROUPS

RECOVERY for pregnant and postpartum women

RECOVERY for patients with chronic kidney disease

RECOVERY Privacy Notice for Trial Staff

COLLABORATORS' MEETING

Slides presented at the collaborators' meeting on 20 & 21 April 2020

Slides presented at the collaborators' meetings on 6 & 7 April 2020

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

- 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 = the same

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New trial design

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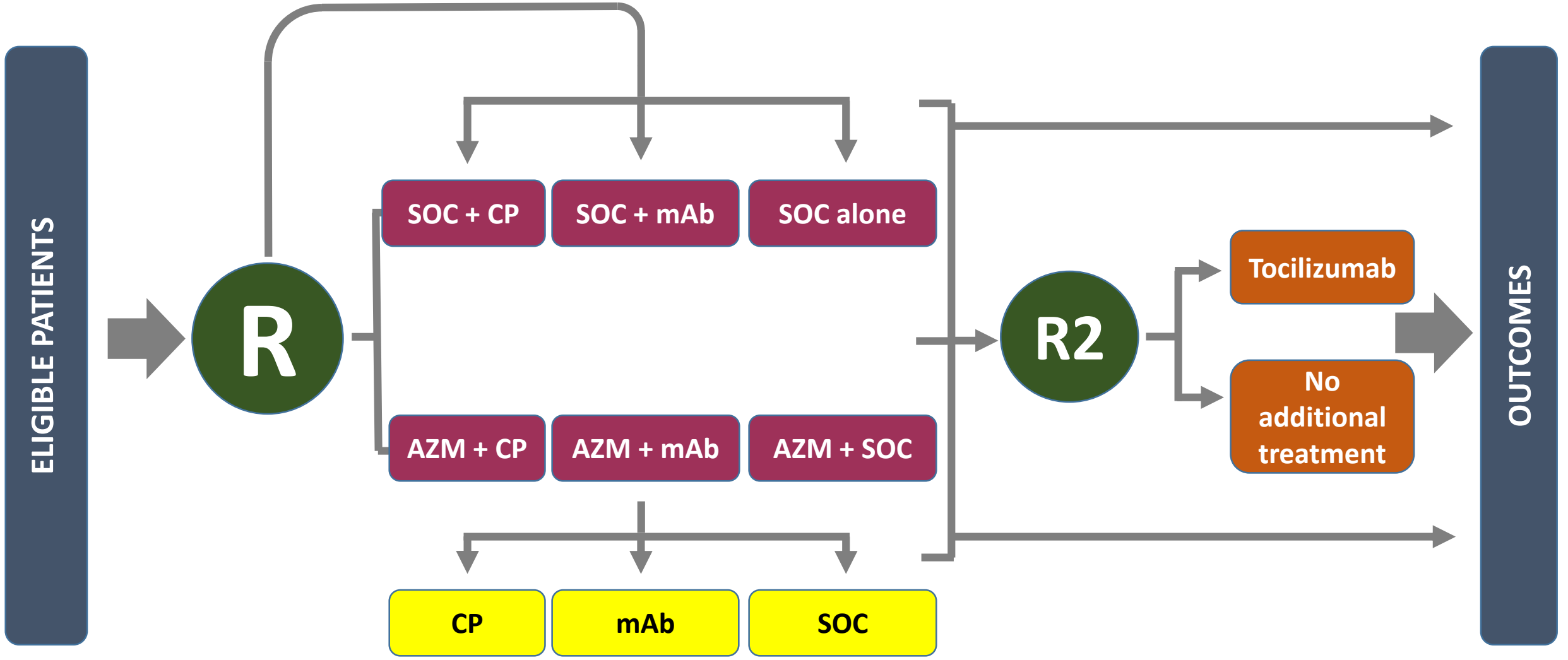
Randomised Evaluation of COVID-19 Therapy



Use of drugs in pregnancy

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Annex A: Trial drugs in pregnancy and during lactation

All trial drugs have been used in pregnant women with pre-existing medical disorders where benefits outweigh the risks to fetus or woman, including in the first trimester. The existing data related to each drug is summarized below.

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Azithromycin
Azithromycin is used in pregnancy to treat genital Chlamydia trachomatis infection, with a Cochrane systematic review and meta-analysis reporting fewer gastrointestinal side-effects compared to erythromycin, and inconsistent results on risk of preterm birth, preterm rupture of membranes, perinatal mortality and low birthweight, confounded by the indication for treatment.[1] A recent systematic review and meta-analysis of all macrolide antibiotics acknowledges potential bias in child outcome reports due to treatment indication.[2] The UK Teratology Information Service monograph concludes that there is no definitive evidence linking azithromycin with increased risk of miscarriage or congenital malformations (https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-MACROLIDES-IN-PREGNANCY/). Azithromycin is detected in only low levels in breastmilk and is not expected to cause adverse events in breastfed infants (reviewed in Lactmed database: www.ncbi.nlm.nih.gov/books/NBK501200/) Azithromycin has also been used in several trials in preterm infants as a prophylactic treatment to prevent bronchopulmonary dysplasia.[3]

Additional randomisation intervention: Convalescent plasma (prepared with Dr Sue Pavord, Consultant Haematologist)
Convalescent plasma is plasma from people who had confirmed COVID-19 (SARS-Cov-2) infection, and have now recovered and been free of the infection for 28 days. The plasma contains antibodies that their immune systems have produced in fighting the virus. It is hoped that giving this plasma will help speed up recovery of a patient with active infection and improve their chances of survival. Plasma is already used as a treatment in pregnant patients who are bleeding,[4] or have particular blood conditions.[5, 6] The plasma being used in this trial is from a selected donor and hopefully contains anti-SARS-Cov-2 antibodies, but is otherwise no different. Plasma infusions can occasionally cause side effects. Mostly this is a rise in temperature, itching or a rash, and in very extreme cases, anaphylaxis. Other potential complications include breathlessness and changes in blood pressure. Monitoring of pulse and blood pressure takes place before and after the infusion. There is no risk of miscarriage or fetal loss, preterm birth, preterm rupture of membranes, perinatal mortality or low birthweight, from plasma transfusions and there are no concerns with breast feeding.

Second randomisation intervention: Tocilizumab
Two pharmaceutical global safety registry database studies have reported on tocilizumab use in pregnancy, including outcomes from 288 pregnancies [7] and 61 pregnancies,[8] typically for rheumatoid or other arthritides, and with the majority having received the drug in the first trimester. These data suggest that the rates of congenital abnormality, spontaneous pregnancy loss and other adverse outcomes were not higher than in the general population.[8] Small studies have shown that tocilizumab is transferred to the fetus with serum concentrations approximately 7-fold lower than those observed in maternal serum at the time of birth.[9] Very low concentrations of tocilizumab are identified in breast milk and no drug is transferred into the serum of breast fed infants.[9, 10] Women should be advised that if treated after 20 weeks' gestation, their infant should not be immunised with live vaccines (rotavirus and BCG) for the first 6 months of life. All non-live vaccinations are safe and should be undertaken.[11]

New information for women

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RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)

for pregnant and breastfeeding women

Pregnancy leads: Prof Lucy Chappell, Prof Catherine Williamson, Prof Marian Knight

2. **Where can I find information specifically written for pregnant women about the drugs?**
   The links below are provided with permission from the bumps (best use of medicines in pregnancy) website, who have developed information leaflets for each of the drugs used in the RECOVERY trial. The bumps website and information are provided by the UK Teratology Information Service (UKTIS), a not-for-profit organisation funded by Public Health England on behalf of the UK Health Departments.
   - Azithromycin: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Azithromycin/
   - Tocilizumab: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Tocilizumab/

Follow-up = the same, + linkage

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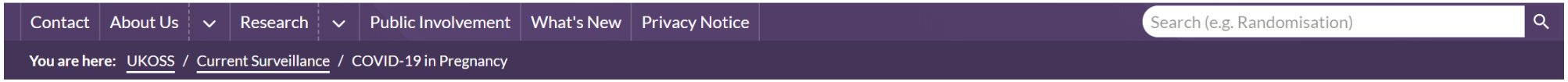
NPEU

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

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

- 20 antenatal women recruited (to end Sept)

Next steps

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

Q&A

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