Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting

29/30th June 2020

Agenda

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1. Introductions
2. Update on progress
3. Hydroxychloroquine
4. Dexamethasone
5. Lopinavir-ritonavir
6. Future plans
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

Current trial design

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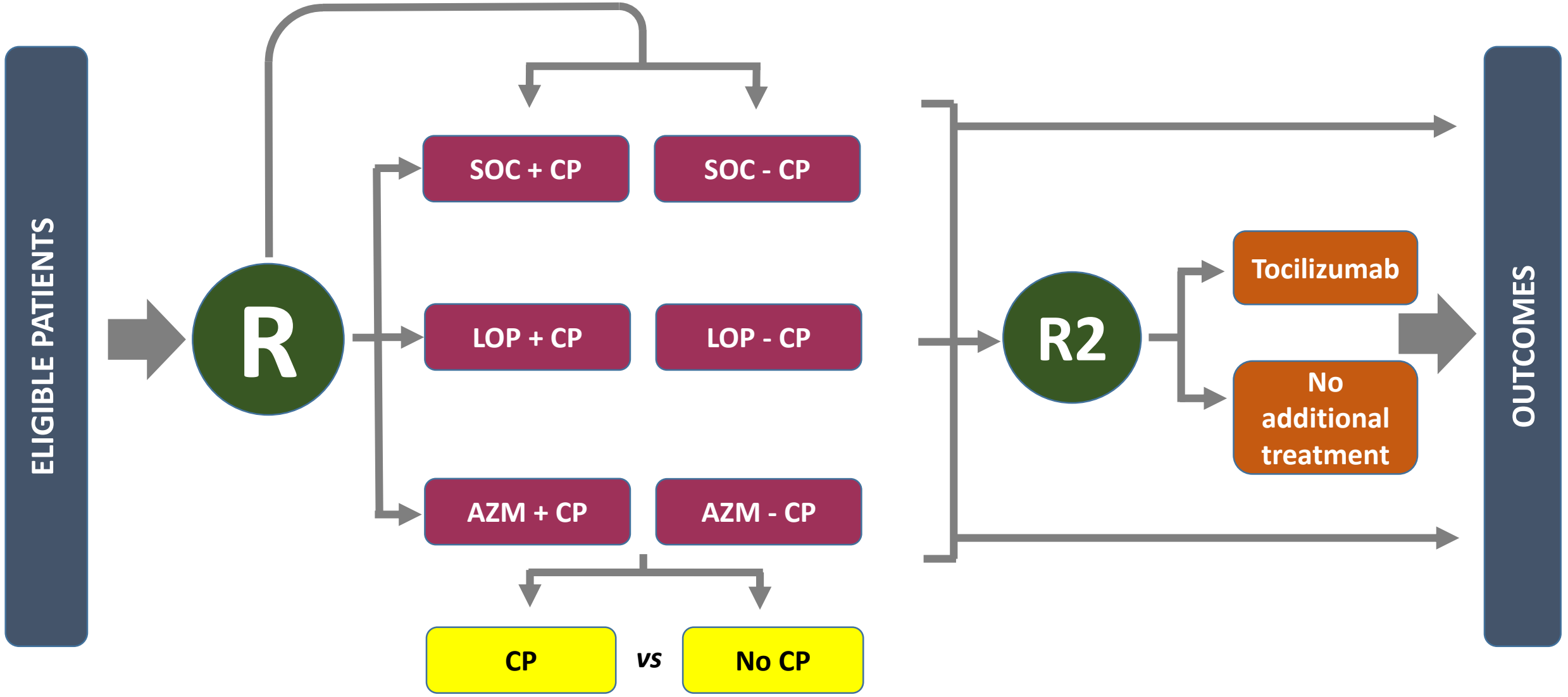

Recruitment by site and by time

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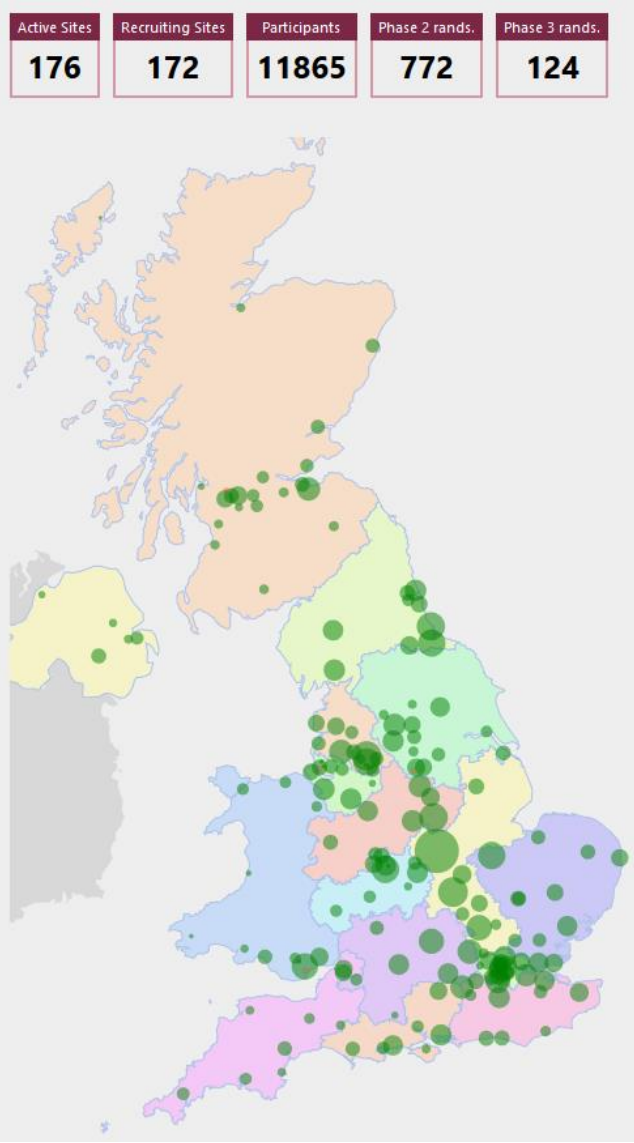

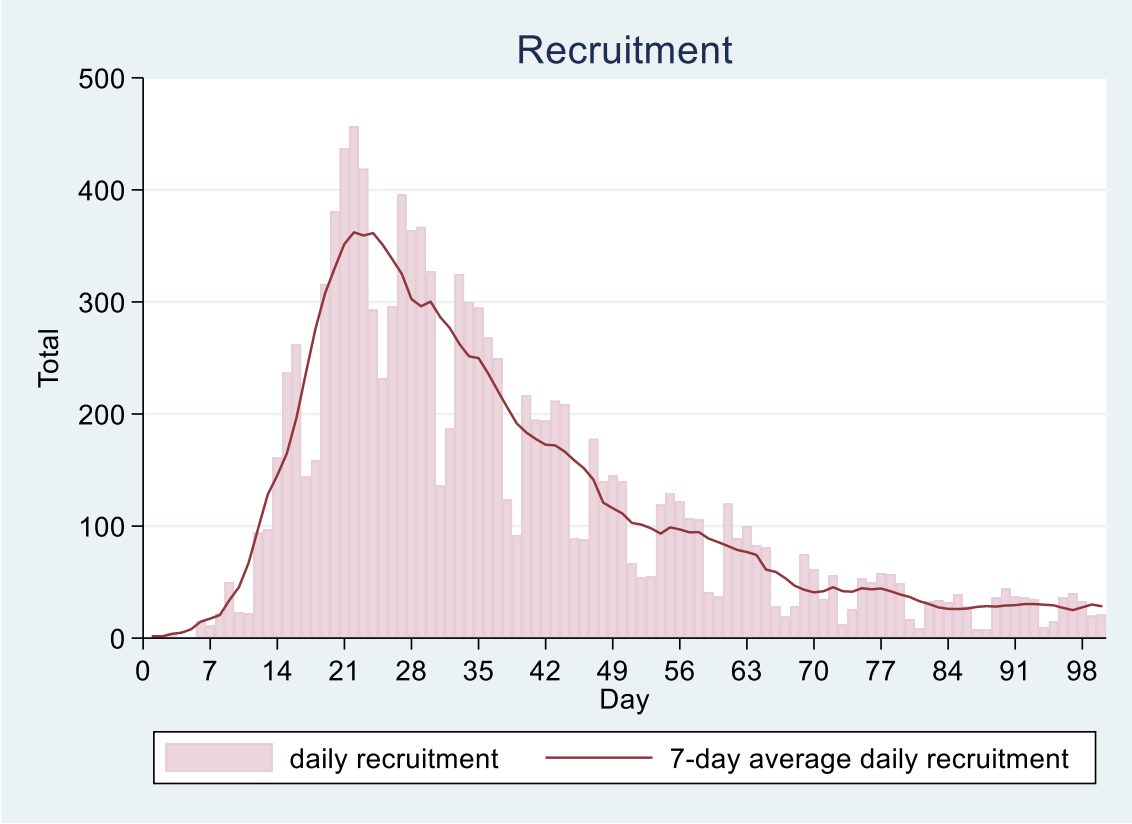

Recruitment: the first 100 days

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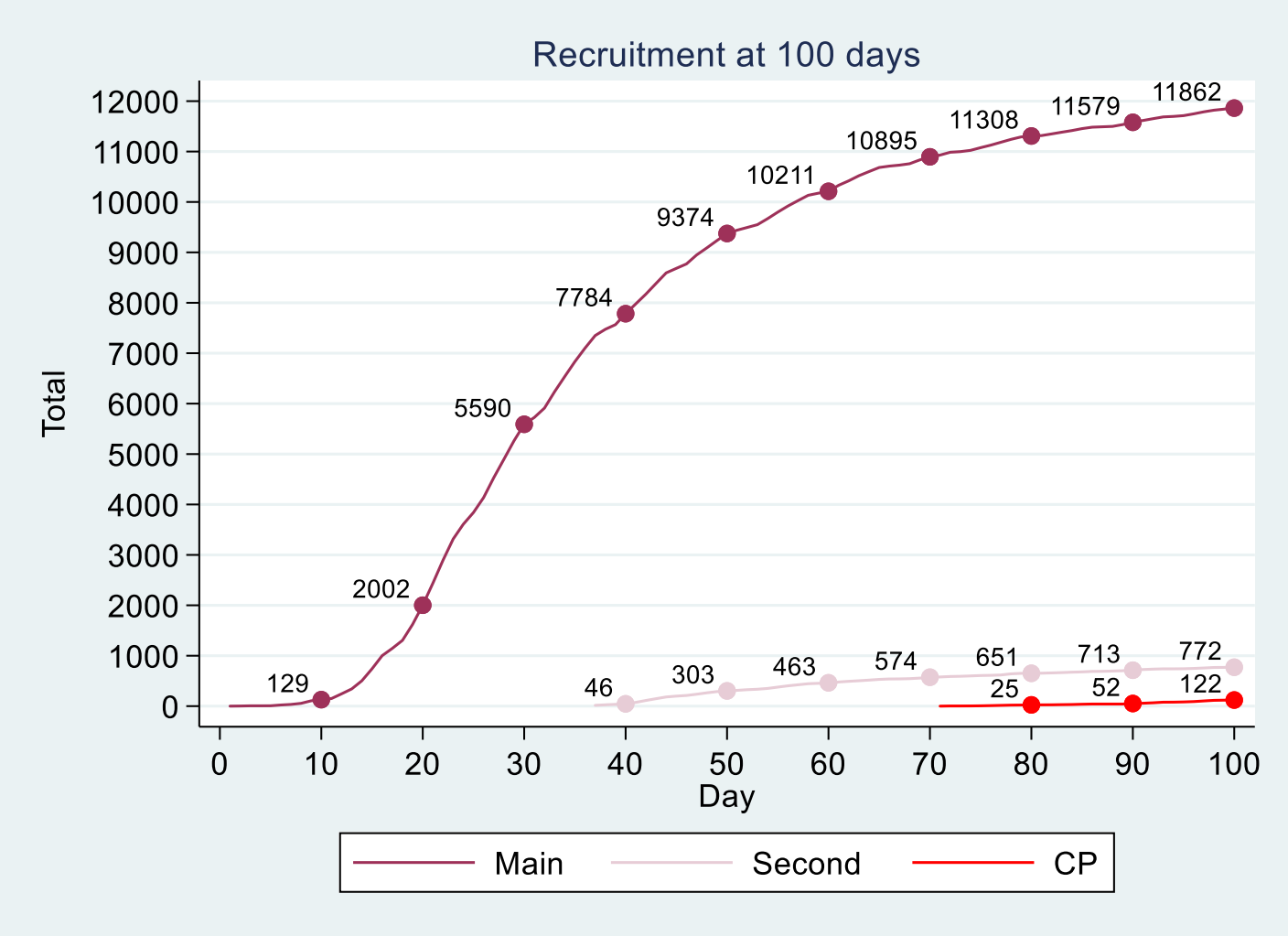

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RESULTS AND IMPLEMENTATION

Hydroxychloroquine

- Added to protocol on 21 March 2020
- Recruitment stopped on 5 June (+76 days)

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Statement from the Chief Investigators of the Randomised Evaluation of COVid-19 thERapY (RECOVERY) Trial on hydroxychloroquine, 5 June 2020

No clinical benefit from use of hydroxychloroquine in hospitalised patients with COVID-19

- US FDA revoked Emergency Use Authorisation on 15 June (+86 days)

Dexamethasone

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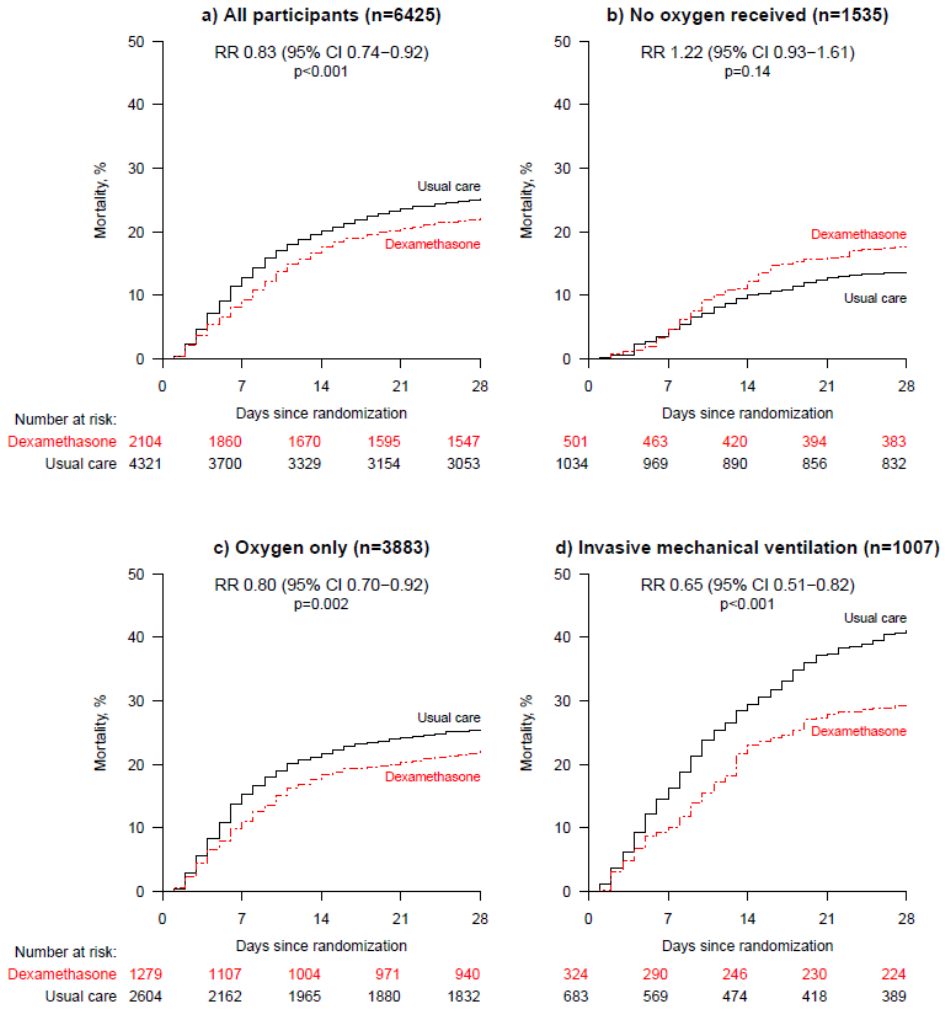

- Included in original protocol (13 March)
- Recruitment stopped on 8 June (+87 days)
  - Stopped blind to outcome because recruitment sufficient

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Oxford University News Release

EMBARGOED UNTIL 16 June 2020, 13:00 (UK Time)

Low-cost dexamethasone reduces death by up to one third in hospitalised patients with severe respiratory complications of COVID-19

- Results announced on 16 June (+95 days)

Dexamethasone

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- The guideline writers are going to be busy…

Table 5 | Recommendations for use of corticosteroids for covid-19 in global guidelines produced early in pandemic

Origin	Corticosteroid recommendations	Evidence base	Antimicrobials notes
WHO	Corticosteroid therapy contraindicated	Stockman LJ et al,[27] Rodrigo C et al,[28] Delaney et al,[29] Arabi YM et al[30]	Give empirical antimicrobials to treat all likely pathogens causing SARI
Italy	Not recommended for confirmed covid-19 patients, but low dose dexamethasone may be considered in patients with confirmed ARDS on ICU clinicians' indication	World Health Organization interim guidance,[9] Villar J et al[31]	Add antibiotic (empirical or targeted) according to clinical indications, health policies, or protocols in use
US CDC	Corticosteroids should be avoided unless indicated for other reasons (eg, COPD exacerbation or septic shock)	Zumla A et a,l[32] Arabi YM et al,[30] Russell et al,[33] Metlay JP et al[34]	
India	Not recommended for viral pneumonia or ARDS outside of clinical trials, unless indicated for other reason	No link to supporting evidence provided	Antibiotics not recommended/covered
Turkey	Not recommended routinely	No link to supporting evidence provided	Give empirical antimicrobials to treat all likely pathogens causing SARI
South Korea	Steroids not indicated in general but may be considered for other conditions, such as septic shock	No link to supporting evidence provided	Empirical antimicrobials for possible pathogens are recommended
France	Steroids not indicated for SARS-CoV-2 infection alone	Stockman LJ et al[27]	Routine use of antibiotics for treatment of covid-19 not recommended. However, antibiotics may be used if accompanying bacterial infection is suspected
Brazil	Not recommended for viral pneumonia or ARDS outside of clinical trials, unless indicated for other reasons	No link to supporting evidence provided	
Taiwan	Not recommended for viral pneumonia or ARDS outside of clinical trials, unless indicated for other reasons	No link to supporting evidence	Systematic coverage of bacterial infection/superinfection recommended in severe forms
Indonesia	Not recommended for viral pneumonia or ARDS outside of clinical trials, unless indicated for other reasons	No clear link to supporting evidence	
Spain	Not recommended	No clear link to supporting evidence	Give empirical antimicrobials to treat all likely pathogens that cause SARS
Malaysia	Not recommended unless indicated for other reasons (eg, COPD, septic shock)	No clear link to supporting evidence	Consider giving empirical antibiotics to treat other possible bacterial infection
Germany	Not recommended without clear indication	No clear link to supporting evidence	Give empirical antibiotics based on likely aetiology

ARDS=acute respiratory distress syndrome; COPD=chronic obstructive pulmonary disease; ICU=intensive care unit; SARI=severe acute respiratory illness; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Dagens *BMJ* 2020

Dexamethasone: into practice <100 days after the trial started

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Department of Health & Social Care

MHRA

NHS

COVID-19 Therapeutic Alert

Original Issue date: 16 June 2020.
This version published on 24 June 2020. The paragraph at the end of the Clinical Guidance section has been updated to include updated information on the interaction between remdesivir and dexamethasone. This update appears in red text.
Alert ref: CEM/CMO/2020/026

Dexamethasone in the treatment of COVID-19
Implementation and management of supply for treatment in hospitals

Summary

For immediate action

Dexamethasone has been demonstrated to have a clear place in the management of hospitalised patients with COVID-19.

There were no excess harms identified in using this dose of dexamethasone in this patient population. Dexamethasone was not used in pregnant women.

Clinicians should therefore consider dexamethasone for the management of hospitalised patients with COVID-19 who require oxygen or ventilation.

Out of hospital treatment is not appropriate.

There is no current or anticipated constraint on supply of the medicine in the UK.

World Health Organization

Health Topics | Countries | Newsroom | Emergencies

Home / Newsroom / Detail / WHO welcomes preliminary results about dexamethasone use in treating critically ill COVID-19 patients

WHO welcomes preliminary results about dexamethasone use in treating critically ill COVID-19 patients

16 June 2020 | News release

The World Health Organization (WHO) welcomes the initial clinical trial results from the United Kingdom (UK) that show dexamethasone, a corticosteroid, can be lifesaving for patients who are critically ill with COVID-19. For patients on ventilators, the treatment was shown to reduce mortality by about one third, and for patients requiring only oxygen, mortality was cut by about one fifth, according to preliminary findings shared with WHO.

The benefit was only seen in patients seriously ill with COVID-19, and was not observed in patients with milder disease.

"This is the first treatment to be shown to reduce mortality in patients with COVID-19 requiring oxygen or ventilator support," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "This is great news and I congratulate the Government of the UK, the University of Oxford, and the many hospitals and patients in the UK who have contributed to this lifesaving scientific breakthrough."

Lopinavir-ritonavir

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- Lopinavir is a protease inhibitor used to treat HIV
  - Combined with ritonavir as ritonavir inhibits metabolism of lopinavir so increases its half-life
- Found to inhibit SARS-CoV *in vitro*
- Also inhibits MERS-CoV *in vitro* and in animal model

Lopinavir-ritonavir: conclusions

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- No meaningful effect on all-cause mortality by 28 days
- No evidence of any difference in effect in different types of participant (e.g. those with earlier stage disease)

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TOCILIZUMAB

Tocilizumab

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- Added to protocol on 14 April as a second randomisation for deteriorating participants
  - Hypoxia (or significant systemic disease with persistent pyrexia in children)
  - Inflammation (CRP ≥75 mg/L)

- Nearly 800 participants recruited to date

- Two other tocilizumab trials due to present results at the end of July
  - COVACTA: Roche's own trial of 450 participants
  - BACC study: 243 participants

Tocilizumab

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- Other trials very unlikely to have power to demonstrate effect on mortality
- Effects of tocilizumab in presence of dexamethasone is now an important question
- Please keep recruiting into this arm
- If your site is not included yet but would like to be, please e-mail recoverytrial@ndph.ox.ac.uk

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FOLLOW-UP

Completeness is key

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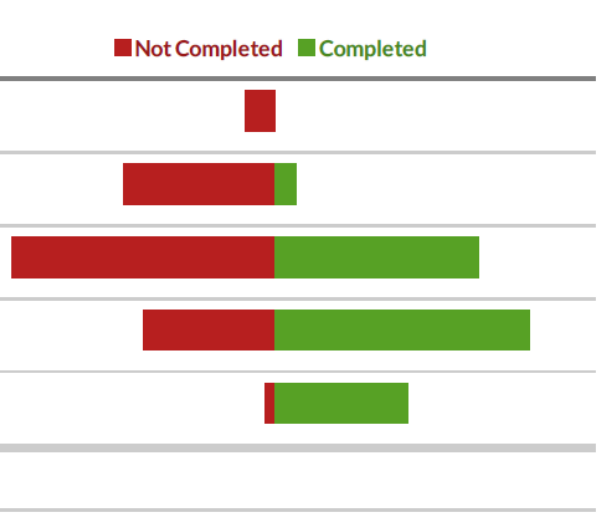
- Weekly reminders will be sent out by trial team to PI and staff with responsibility for completing Follow-up forms, highlighting participants randomised >28 days ago without complete form

- 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**



Follow-up completeness

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- Particular plea for the **72 hour convalescent plasma safety forms**
- These are used by DMC to assess safety of convalescent plasma
- Need to be completed for participants receiving convalescent plasma **and** those assigned standard care in that comparison

Data queries

- Trial management team (Lucy, Karen, Sarah, Richard, Wojtek and Ayten) may be in touch about “data queries”

- Please respond as quickly as possible in order to get data ready for publications

SAE reporting

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- Please remember that adverse events only need to be reported if they are **both**:
  - SERIOUS (e.g. prolong admission, require significant intervention to avoid life-threatening situation)

  AND
  - RELATED with reasonable probability to study treatment

- Please contact coordinating centre if such an event occurs.
- Please do not use “yellow card” system

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FUTURE PLANS

Current protocol

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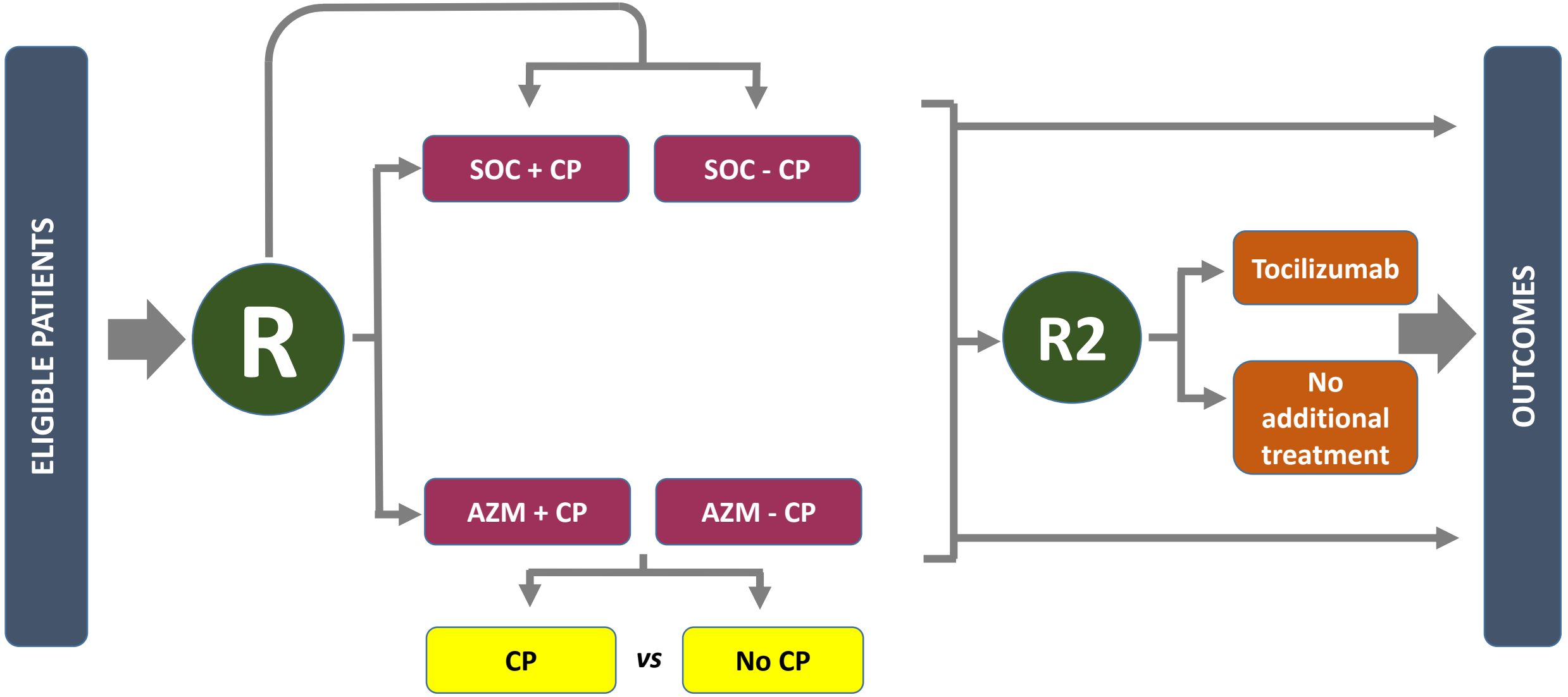

Future protocol

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- Purpose of a platform trial is that drugs may be added
  - Anticoagulation comparison
  - Synthetic antibodies

- Although pandemic is relatively quiet in the UK, this allows an opportunity to prepare treatments for large-scale implementation in a ‘second wave’
  - Convalescent plasma is an example of this

Carry on recruiting!

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- Need to continue recruitment and collection of follow-up information to provide DMC with information about efficacy and safety of study treatments

- As admission rates fall, please focus efforts on recruiting as many admitted patients as possible

- Thank you!

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting for Pregnancy

29th June 2020 4pm

RECOVERY for pregnant women

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1. Update on adaptions
2. Follow-up
3. Update on progress
4. Future plans
5. Q&A

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’

Notes on eligibility

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- What about women with a positive covid-19 swab result but initially admitted for another reason…?
- 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 reasonable to provide the 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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Initial trial design

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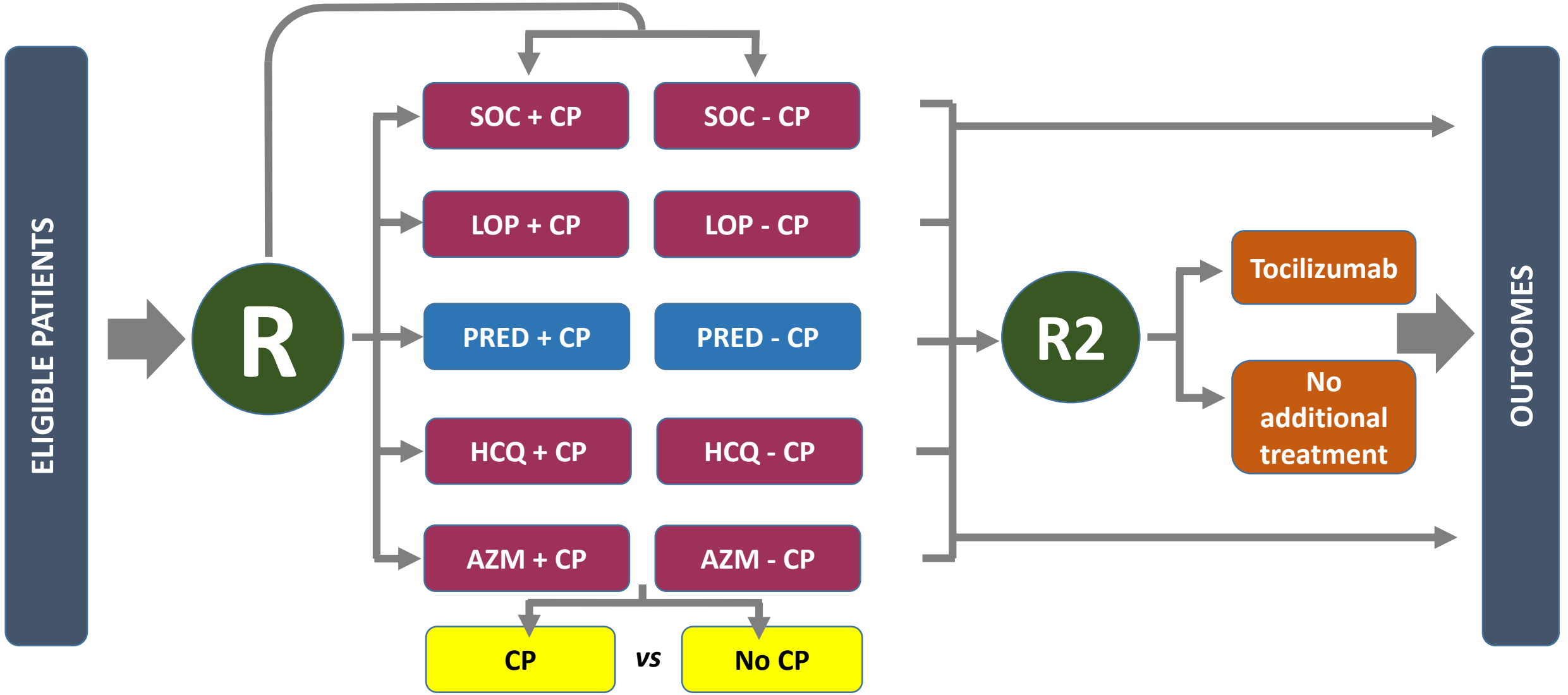

Hydroxychloroquine arm stopped

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Steroid arm beneficial (on O2)

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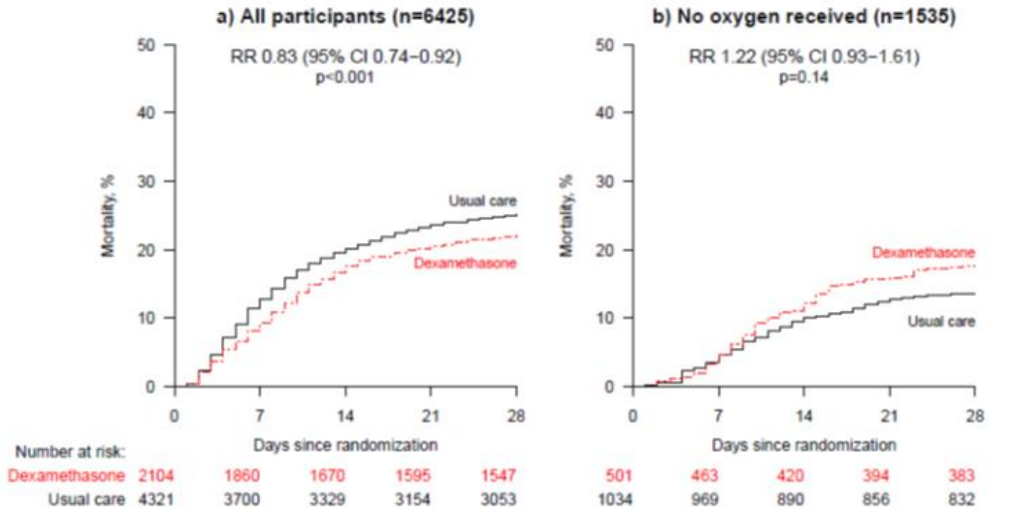

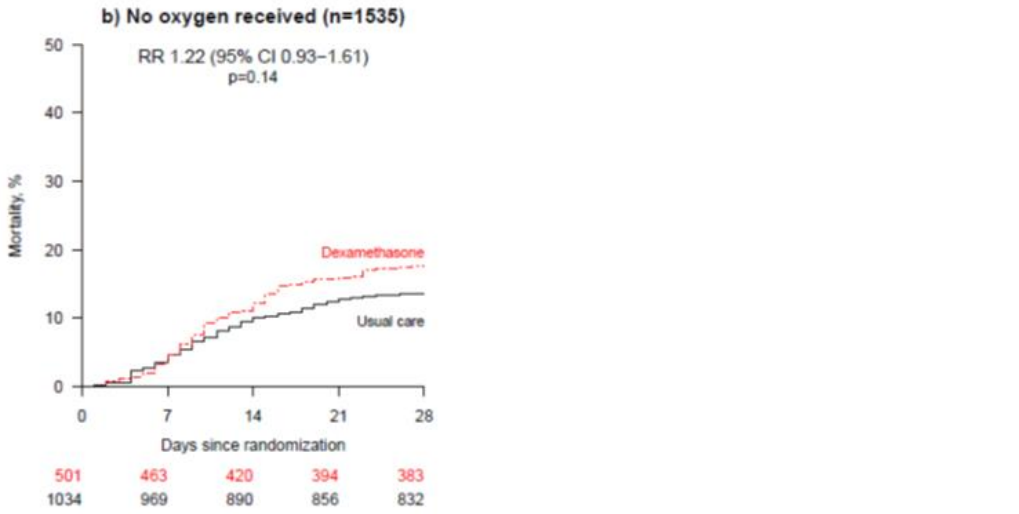

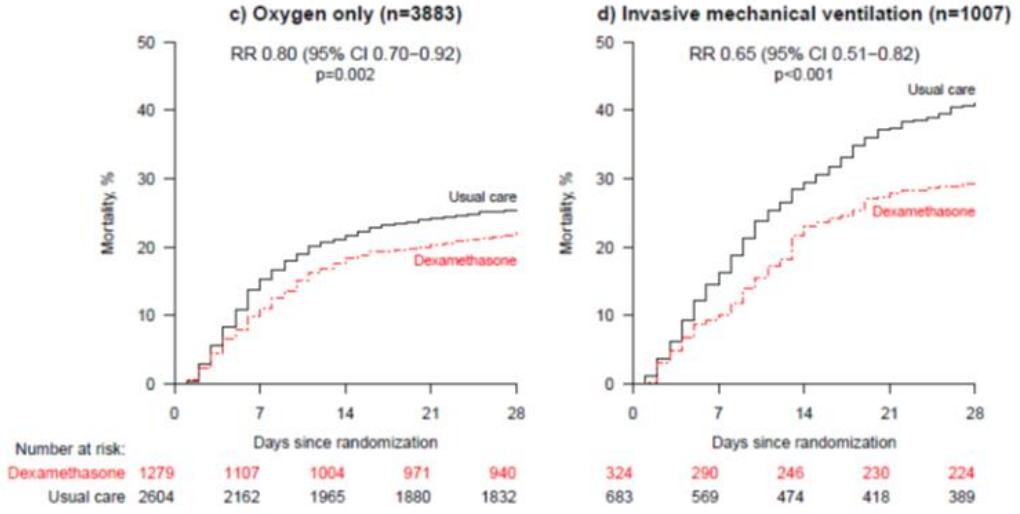

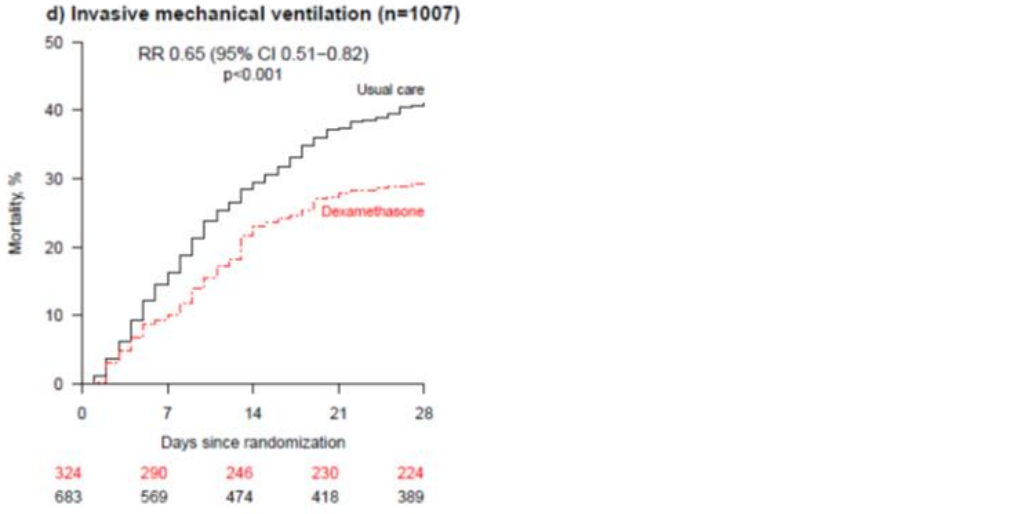

Updated RCOG guidelines: steroids

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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).

Recent trial design

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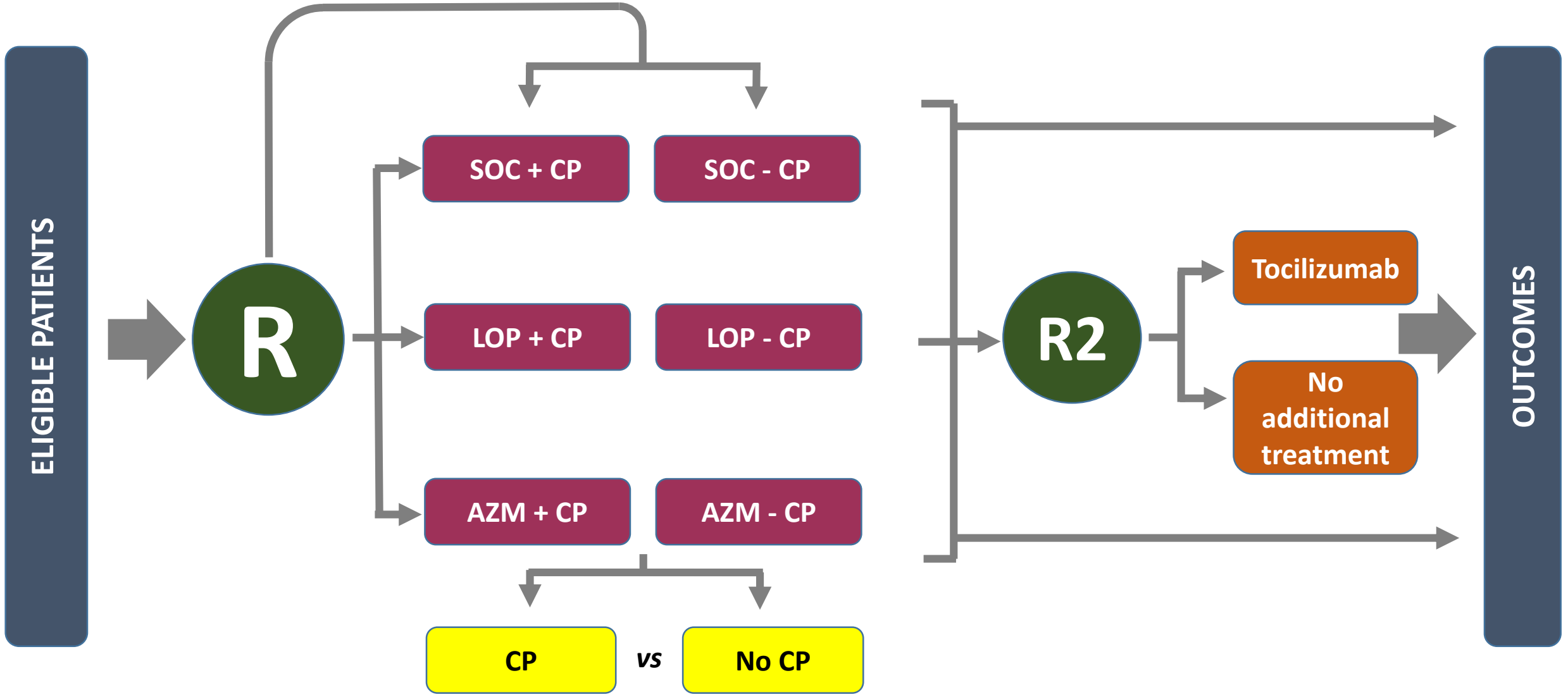

Lopinavir-ritonavir arm stopped

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Current protocol (as of today)

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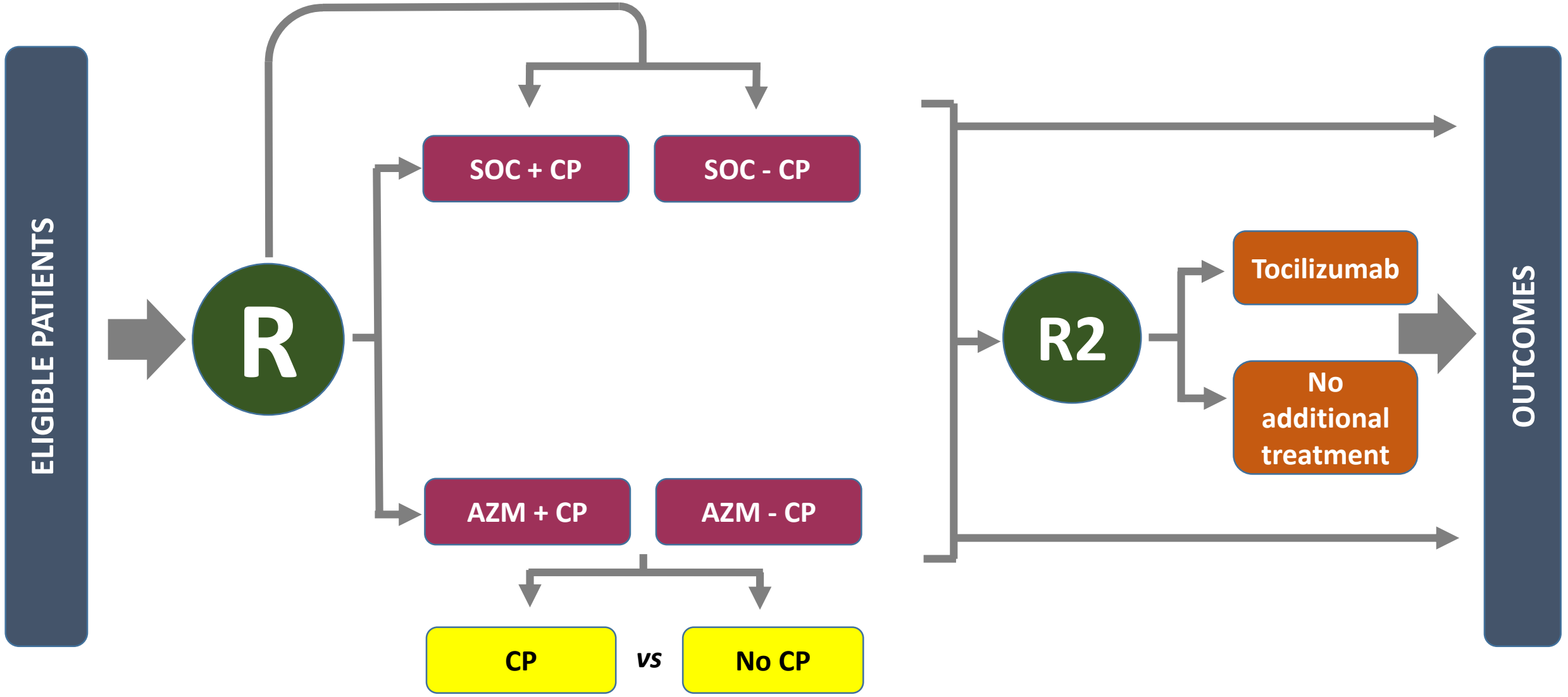

Use of drugs in pregnancy

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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.

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.

Lopinavir-Ritonavir
Lopinavir-ritonavir (400/100mg) treatment is used throughout pregnancy to treat HIV, with treatment reducing viral load and vertical transmission.[1] Elevated liver transaminases and impaired glucose tolerance should be screened for, but are not commonly seen in pregnancy. Some studies reported increased rates of late preterm birth in lopinavir-ritonavir-treated women compared to other protease inhibitors .[2] However, a systematic review that included nine studies (2,675 lopinavir/ritonavir-treated pregnant women with HIV) and considered preterm birth, low birth weight and stillbirth did not suggest any safety concerns.[3] Ergometrine should be avoided in women receiving lopinavir-ritonavir. Lopinavir and ritonavir are detected in breast milk, but the levels are considerably lower than maternal blood levels, and most studies have reported very low infant blood concentrations,[4] as reviewed in the Lactmed database (www.ncbi.nlm.nih.gov/books/NBK501550/).

Hydrocortisone/ prednisolone
Prednisolone 40 mg PO od or, in women unable to take oral medicine, hydrocortisone 80mg IV BD are recommended instead of dexamethasone treatment in light of accumulating evidence that repeated doses of dexamethasone have deleterious effects on long-term neurodevelopment of the fetus.[5-7] While 90% dexamethasone is transferred transplacentally to the fetus, both hydrocortisone and prednisolone are converted by 11β-hydroxysteroid dehydrogenase to inactive glucocorticoids and considerably less drug is transferred to the fetus. Glucocorticoids can worsen maternal glycaemic control, so blood glucose should be checked and managed appropriately. Otherwise there is no convincing evidence that prednisolone use is associated with increased rates of adverse pregnancy outcomes when taken in the first trimester or later pregnancy.[8] Very low concentrations of prednisolone enter breastmilk. There is a paucity of data about pharmacological use of hydrocortisone, but it is likely that this is also safe when breastfeeding,[8] as also reviewed in the Lactmed database (www.ncbi.nlm.nih.gov/books/NBK501076/). Prednisolone (or hydrocortisone) should be used in breastfeeding women, in preference to dexamethasone.

Hydroxychloroquine
Several studies have provided reassuring safety data for the use of hydroxychloroquine (HCQ) in the first trimester, later pregnancy and when breastfeeding.[8, 9] The doses used in the RECOVERY trial are higher, but acceptable given the good safety profile of HCQ. Reports of retinopathy, nephrotoxicity, myopathy and cardiomyopathy have all been reported after long-term (more than 6 months) treatment, rather than the short course proposed here.

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.[10] A recent systematic review and meta-analysis of all macrolide antibiotics acknowledges potential bias in child outcome reports due to treatment indication.[11] 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.[12]

Second randomisation intervention: Tocilizumab
Two pharmaceutical global safety registry database studies have reported on tocilizumab use in pregnancy, including outcomes from 288 pregnancies [13] and 61 pregnancies,[14] 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.[14] 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.[15] Very low concentrations of tocilizumab are identified in

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/

Convalescent plasma

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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,[18] or have particular blood conditions.[19, 20] 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.

Follow-up = the same, + linkage

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Search (e.g. Randomisation)

You are here: UKOSS / Current Surveillance / COVID-19 in Pregnancy

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

- 16 antenatal women recruited + more postnatal women (to be determined)

Update from UKOSS this week

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Update from UKOSS this week

Nuffield Department of POPULATION HEALTH
Medical Sciences Division
UNIVERSITY OF OXFORD

UKOSS
UK Obstetric Surveillance System

Notifications by week

UKOSS: SARS-CoV-2

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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

WHAT THIS STUDY ADDS

More than half of pregnant women admitted to hospital with SARS-CoV-2 infection in pregnancy were from black or other ethnic minority groups

Most women did not have severe illness, and most were admitted in the third trimester of pregnancy

Transmission of infection to infants of infected mothers may occur but is uncommon

the bmj | *BMJ* 2020;369:m2107 | doi: 10.1136/bmj.m2107

Where are we now: positives

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- Equity of access to the trial
- Readiness for future cases
- Link with UKOSS for outcomes
- Research working across disciplines within sites
- Strong ongoing support from RH&C teams
- Blueprint for rolling out a trial in future

Where are we now: challenges

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Previous

- Site set-up, including pharmacy
- Opened after peak

Ongoing

- Lower number of cases in maternity vs. rest of hospital (but still ongoing)
- Cases reducing generally (but still ongoing)
- Uncertainty over different presentations/ overlap with normal obstetric presentations
- Need to identify postnatal women in RECOVERY – work ongoing

Moving forward

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If reporting to UKOSS, check: can we offer the trial…?

Lessons learned from recruiting sites:

- Engaged PI
- Proactive research midwives and nurses
- Good liaison with main site PI (e.g. sharing information)
- Avoidance of ‘gatekeeping’
- Understanding fetal safety data (see UKTIS)
- Embedding into usual clinical care (aim of RECOVERY trial)

Q&A

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