Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

REGN-COV2 Q&A
14-16th October 2020
New trial design

**Outcomes**
- Tocilizumab
- No additional treatment

**Eligible Patients**
- R
- R2

**Treatments**
- SOC alone
- SOC + mAb
- SOC + CP
- AZM + SOC
- AZM + mAb
- AZM + CP
- mAb
- SOC
- CP
Several companies are now producing monoclonal antibodies (mAbs) against SARS-CoV-2 “spike” protein
REGN-COV2

• 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

• 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...

Welcome to the BBC

LIVE Trump receives treatment as new cases emerge
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) 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
Administration

• REGN-COV2 is reconstituted in 250 mL bag of normal saline and infused over 60 minutes via a 0.2-0.22 micron low protein binding filter.

• Does not necessarily require administration 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.
Preparation

• There is nothing in the SPS national guidance (https://www.sps.nhs.uk/wp-content/uploads/2016/12/mAb-Products-5th-Edition-2015.pdf) that states where mAbs should be prepared. The choice of preparation area and therefore isolator should be determined by the product.

• A risk assessment using nationally recognised tools and advice was sought from Regional QA. In their opinion, in the absence of evidence/lack of data due to how new these mAbs are, they would suggest that operator protection should be provided, as well as microbiological protection of the final product.

• This is not a licensed mAb and there is very little data on the occupational exposure and potential impact on the staff preparing.

• MAbs should be prepared in line with SPS yellow cover document on a campaign basis with clean down between this product and another drug, to reduce or minimise the risk of product cross-contamination.
Spill Kit

• REGN-COV2 is not cytotoxic
• The components contained within a cytotoxic spill kit can be used to clean up a monoclonal antibody spill
• If sites have a non-cytotoxic spill kit which covers monoclonal antibody spills or a specific monoclonal antibody spill kit, then they can use those kits instead