30.03.2020

"At what point might meaningful results from clinical trials be available?"

RECOVERY TRIAL

Randomised controlled trial (5 arms currently) in hospitalised adults.
Target sample size = not specified

Conclusion: Results could be available for the beginning of June based on assumptions below.

The key parameter is the proportion of patients enrolled. Above assume 75% of patients are enrolled. If the uptake rate is as low as 50% or 25%, the required sample size would not be reached by the tail end of the epidemic.

Assumptions

- The relative risk reduction in the treatment arm is 25% (RR= 0.75)
- The event rate (death) is 20% in the control arm: based on Imperial College projections, the overall mortality rate for hospitalised adults aged 20+ years by the end of the epidemic will be 6586/35070 (19%).
- For 2:1:1:1:1 allocation, 90% power, 5% 2-sided overall alpha, 7116 patients would be required.
- If 75% of patients are enrolled the sample size of 7116 required to detect a difference in one of the arms would be achieved during the week commencing 04/05/2020. A lag of 28 days would be needed to allow for outcome data collection and analysis (for last patient recruited).

PRINCIPLE

Randomised controlled trial (2 arms currently) in primary care
Target sample size = 3000

Conclusion: Depending on enrolment and event rates, meaningful results from the PRINCIPLE clinical trial may be available in 5 to 10 weeks.

Aim to recruit 3000 participants in the first instance but will continue to recruit until superiority or futility threshold met.

Assumptions

- General practices – 150 opened in week 1 and 300 in week 2, and by week 3 500 practices open.
- Recruit around 250 to 500 patients per week