NUFFIELD DEPARTMENT OF **PRIMARY CARE** HEALTH SCIENCES Clinical Trials Unit

Weekly Newsletter - 8th July 2021



New Treatment Arm! Ivermectin—Background & Rationale

- Ivermectin is an anti-parasitic drug that is licensed in the UK for topical use in the treatment of rosacea.
- Oral Ivermectin is approved by the US FDA and is on the World Health Organisation (WHO) Essential Medicines List.
- Ivermectin is well tolerated in humans and has a good safety profile.
 - Ivermectin has in vitro activity against SARS-CoV-2, and
 emerging clinical evidence from multiple small trials suggest it
 may effectively reduce SARS-CoV-2 viral loads, reduce time to
 recovery, and reduce mortality among people with COVID-19.
 However, data from large, robust clinical trials is lacking.

Ivermectin Dose Regimen

Ivermectin tablets (3mg) are for oral administration.

Tablets to be taken as one dose each day for 3 days at 300mg/kg body weight.

Up to maximum of 30 mg tablets can be taken with water, but no food should be taken two hours before or after administration, as the influence of food on absorption is not known.



PRINCIPLE Trial—

Award Nominations



The PRINCIPLE Trial has been highly commended at the Health Data Research UK Awards for the way in which patient data is utilised so participants are contacted about the trial soon after receiving a positive test result.

PRINCIPLE was recognised by the judges of the Impact of the Year Award as a leading example of the innovative use of primary care data and settings whilst working at pace and scale.

Useful Reminder—Age Eligibility Criteria

Trial arm	Eligible Age Group (meeting other eligibility criteria)
Usual Care	Aged 18 -64, with a certain underlying health condition, OR who have short- ness of breath as part of their COVID-19-like illness. OR aged 65 and over
Usual Care + Favipiravir	Aged 50 – 64 with a certain underlying health condition, OR who have short- ness of breath as part of their COVID-19-like illness. OR aged 65 and over
Usual Care + Ivermectin	Aged 18- 64 with a certain underlying health condition, OR who have short- ness of breath as part of their COVID-19-like illness. OR anyone aged 65 or over

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