Ivermectin

RECOMMENDATION
We recommend against the use of ivermectin as COVID-19 prophylaxis for the general population. (Very low quality of evidence; Strong recommendation)

We recommend against the use of ivermectin for COVID-19 as post exposure prophylaxis for household contacts of confirmed COVID-19 patients (Very low quality of evidence; Strong recommendation)

We recommend against the use of ivermectin for COVID-19 as prophylaxis for healthcare workers. (Very low quality of evidence; Strong recommendation)

Consensus Issues
The studies included in the review have very serious or high risk of bias. In particular, the study by Elgazzar et al. (2021) had a very low overall quality of evidence due to the risk of bias and serious imprecision from the wide 95% confidence interval (CI). The Shoumann et al. (2021) study also has a serious validity issue due to the premature termination of the control group, and lack of pretermination protocol, thus leading to selective reporting. Lastly, the results of the Chahla et al. (2021) study also have validity issues due to the presence of a co-intervention in the treatment arm. These methodologic limitations leads to uncertainty in the effects of ivermectin.

The panel recognized the high likelihood for its misuse or overuse and the concomitant false sense of security. The panel also stressed that there is a need to have concrete evidence on safety, as well as on the appropriate dose and dosing frequency, which the current very low quality evidence did not provide. Another issue raised was that only a compassionate special permit (CSP) has been granted to two specific hospitals that applied for the permit, despite the current registration of ivermectin products as veterinary treatment for internal and external animal parasites. Hence, there may be legal implications when a positive recommendation to use it as a prophylaxis is issued. The human-grade ivermectin, on the other hand, is still applying for emergency use authorization (EUA) from the Philippine Food and Drug Administration. Considering the vaccine hesitancy of the public, a concern was raised by the panel that if a recommendation to an alternative to the vaccine as prophylactic agent will be made, then people may opt not to get vaccinated, undermining the national vaccination program of the government.
Should ivermectin be used as COVID-19 prophylaxis for the general population?

Evidence Reviewers: Marie Gene D. Cruz, MD; Lea Roselle O. De Castro, MD; Dan Louie Renz P. Tating, MS (cand), RN; Maria Teresa S. Tolosa, MD, D Clin Epi, FPDS

Key Findings
Three very low quality randomized controlled trials (RCT) were found on the use of ivermectin as COVID-19 prophylaxis. Both RCTs showed indirect evidence for the general population, and were also found to have very serious risk of bias particularly on blinding, incomplete outcome, and selective reporting. One RCT showed lower rates of developing COVID-19 related symptoms. Another RCT showed lower RT-PCR-confirmed COVID-19 infection rates in the ivermectin group compared to non-intervention group. Thirdly, one RCT revealed a lower rate of RT-PCR-confirmed COVID-19 in the ivermectin group, however, the administration of a co-intervention in this group poses serious validity issues in the outcome of interest. Mild adverse events were reported such as gastrointestinal upset, fatigue, sleepiness, pruritus, numbness, and burning sensation, all of which did not necessitate discontinuation of therapy.

Introduction
Ivermectin, an anti-parasitic agent used for onchocerciasis and lymphatic filariasis, is currently being investigated as treatment and prophylaxis for COVID-19 due to its potential anti-viral effect against SARS-CoV-2 [1-3]. In an in vitro study by Caly et al. [4], SARS-CoV-2 infected cells that were treated with ivermectin two hours after infection were found to have a 99.98% reduction in viral RNA load on real-time polymerase chain reaction (RT-PCR) after 48 hours. It has been hypothesized that ivermectin inhibits importin α/β1-mediated transport of viral proteins into the host’s cell nucleus, which is also the proposed mechanism of action of ivermectin in other RNA viruses. Given the promising in vitro findings and known safety profile of ivermectin, several clinical trials are now in progress to determine if this repurposed drug may be of significant value in controlling COVID-19 transmission.

Review Methods
Literature search was conducted on electronic databases and clinical trial registries (PubMed, CENTRAL, ClinicalTrials.gov, medRxiv.org, bioRxiv.org, covid-nma.com, COAP Living Evidence on COVID-19, Chinese and EU Clinical Trial Registry), and UpToDate on March 16-18 and April 21, 2021. Terms such as “COVID-19”, “ivermectin”, “prophylaxis” or “prevention” were used during the search. No limitation on language was set. Further review of references of retrieved studies was also done to check for other possible articles.

Studies that involved administration of ivermectin to high-risk contacts of COVID-19 patients such as household members and healthcare workers were included. Study outcomes included were development of COVID-19 infection or symptoms, and adverse events. Any studies that solely involved administration of ivermectin as treatment for COVID-19 patients were excluded.
This search strategy yielded 49 articles in PubMed. Studies cited in meta-analyses and systematic reviews by Kory et al. [5], Bryant et al. [6] and the British Ivermectin Recommendation Development [7] were also searched. After removing duplications, eight full-text articles were retrieved. Only three RCTs were included in the review after assessing for eligibility and methodology (Appendix 1). The six articles excluded in the review were case control and cohort studies, mostly involving healthcare workers [1-3,8-10].

Results
The three completed RCTs were by Elgazzar et al. [11], Shoumann et al. [12], and Chahla et al. [13] (Appendix 1). The multi-center double-blind study by Elgazzar et al. (preprint article) involved populations of COVID-19 patients (n = 400), and their household contacts and healthcare workers (n = 200), aiming on determining the efficacy and safety of ivermectin both as treatment and prevention of COVID-19 infection [11]. The household contacts and healthcare workers recruited for prophylaxis groups (ivermectin group and non-intervention group) had baseline negative RT-PCR results. Only the outcomes of these prophylaxis groups were included in this review. The study by Chahla et al. [13] recruited healthcare and non-healthcare (administrative) personnel from local healthcare centers (n = 234). The intervention group received a combination of ivermectin and iota-carrageenan, while the control group had no prophylaxis. COVID-19 diagnosis for each group was confirmed by RT-PCR. Lastly, the randomized open-label trial by Shoumann et al. [12] recruited asymptomatic household contacts (n = 340) of RT-PCR-confirmed COVID-19 patients. Recruitment was based on normal body temperature and lack of symptoms, and not on negative RT-PCR results, unlike the two RCTs. Only four symptomatic participants in ivermectin group and 12 symptomatic participants in non-intervention group underwent RT-PCR testing, which all had positive results. The study did not discuss the reasons for participant withdrawal.

The overall risk of bias was deemed to be very serious. The study by Elgazzar et al. [11] had blinding issues due to absence of placebo in the control group, unclear allocation concealment, and selective reporting of results due to unavailable data on adverse events. No baseline and outcome data on the subgroups (household contacts and healthcare workers) were presented. Shoumann et al. [12] also lacked blinding and had unclear allocation concealment. Per protocol analysis was made due to exclusion of drop-outs. Furthermore, the premature termination of the control group due to perceived high protective effect of ivermectin was another source of serious bias. Chahla et al. [13] also had issues on blinding and allocation concealment similar to the two RCTs. Administration of a co-intervention in the ivermectin group poses a serious risk of bias as well.

All three studies determined the COVID-19 infection rate as primary outcome within 14-day follow-up period after contact [11-13]. Results were not pooled since the studies had variable outcome definitions (RT-PCR confirmed COVID-19 vs presence of COVID-19 symptoms). The study by Elgazzar et al. [11] showed that the rate of developing RT-PCR confirmed COVID-19 was 2% in ivermectin group compared to 10% in non-intervention group (RR 0.2, 95% CI 0.05 to 0.89). There were no available data on the subgroup analysis between healthcare workers and household contacts. Although with significant protection in the ivermectin group, the confidence interval was wide, and the risk of bias for this study was deemed to be very serious as mentioned above.
Similarly, Chahla et al. [13] looked into the number of patients who tested positive with RT-PCR for COVID-19. However, since a co-intervention in the form of iota-carrageenan spray was also used in the treatment arm, we decided not to combine its results with the earlier study. The incidence of RT-PCR confirmed COVID-19 in the ivermectin plus iota-carrageenan group was 3.4% compared to 21.4% in the control group (RR 0.16, 95% CI 0.06 to 0.45). The study's very serious risk of bias may have also affected the frequency of outcomes.

The second outcome was the development of COVID-19 related symptoms as reported by Shoumann et al. [12] Statistically significant difference between the two groups in favor of ivermectin prophylaxis group (7.4% vs 58.4%, p <0.001) was reported (RR 0.13, 95% CI 0.08 to 0.21). Despite showing clear benefit, the results should be interpreted with caution due to its very serious risk of bias as mentioned above, and its methodological inconsistencies. The study did not use the gold standard test (RT-PCR) both as baseline and as confirmatory test for majority of participants, and prematurely terminated the control arm. The symptom-based approach in COVID-19 diagnosis of Shoumann et al. might have missed an unknown number of asymptomatic carriers.

In terms of adverse events, Chahla et al. [13] had no reported adverse events. Elgazzar et al. [11] did not mention results on adverse events in the preprint article. However, through email correspondence, the author revealed that only minor side effects were observed such as upper gastrointestinal upset, insomnia, and pruritus; no major side effects developed necessitating discontinuation of the drug. Similarly, Shoumann et al. [12] reported mild side effects in 11 (5.4%) subjects in the ivermectin group. Symptoms included diarrhea (1.5%), nausea (1%), fatigue (1%), sleepiness (0.5%), abdominal pain (0.5%), heart burn (0.5%), numbness (0.5%), and burning sensation (0.5%). Though the side effects were mild, statistical analysis showed significant difference (p = 0.018) between the ivermectin group and non-intervention group. These symptoms were similar to the known adverse events from systemic administration of ivermectin as anti-parasitic agent [14].

**Recommendations from Other Groups**

As of this writing, certain agencies have recommended against the use of ivermectin as COVID-19 prophylaxis. In particular, the European Medicine Agency [15] has concluded that the currently available data have not been found to be sufficient to support the use of ivermectin for COVID-19 outside of clinical trials. Other groups such as Infectious Diseases Society of America [16], and Alberta Health Services COVID-19 Scientific Advisory Group [17] have expressed similar recommendations in their latest guidelines on COVID-19 management, citing presence of confounding factors and very low to low certainty of evidence. The National COVID-19 Clinical Evidence Taskforce of Australia [18] has not yet made recommendations on this topic due to insufficiency of well-designed clinical trials. The guideline development group of the World Health Organization [19] has not issued a statement on ivermectin as COVID-19 prophylaxis stating that the topic is not included in the scope of the guidelines.

The US Food and drug Administration (FDA) [20] and Philippine FDA [21] both have not approved the use of ivermectin for COVID-19 prevention. However, as of April 17, 2021, the Philippine FDA
has granted a compassionate use permit to use Ivermectin as COVID-19 treatment to two unnamed hospitals [22,23].

Research Gaps
Majority of the nine ongoing RCTs on ivermectin as COVID-19 prophylaxis in various trial registries have started recruitment, and will be completed as early as April 2021 (Appendix 4). Additionally, two RCTs have already been completed on registry, but all have yet to publish or release their preliminary results (Appendix 3)

References


Ivermectin as COVID-19 Prophylaxis

As of April 21, 2021


Ivermectin as COVID-19 Prophylaxis

As of April 21, 2021


## Appendix 1. Table of Included Studies

<table>
<thead>
<tr>
<th>Study (RCTs)</th>
<th>Population, n</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elgazzar et al., 2021 (preprint)</td>
<td>health care and household contacts of COVID-19 patients; Age 18-80 years n = 200</td>
<td>Ivermectin 0.4 mg/kg BW single oral dose, and another dose after 1 week</td>
<td>No Ivermectin, only usual standard precautions and PPE</td>
<td>Primary outcome: • Prevention of COVID-19 (RT PCR confirmation) Secondary outcome: • Adverse events</td>
</tr>
<tr>
<td>Shoumann et al., 2021</td>
<td>asymptomatic household contacts of confirmed RT-PCR COVID-19 index case; Age ≥ 16 years n = 340</td>
<td>Ivermectin 0.225-0.375 mg/kg: 15 mg/day per orem for subjects 40-60 kg BW; 18 mg/day for 60-80 kg; 24 mg/day for &gt;80 kg, given on D1 and D3 from diagnosis day</td>
<td>No Ivermectin, only usual standard precautions and PPE</td>
<td>Primary outcome • Prevention of COVID-19 by D14 of follow-up (symptom-based) Secondary outcomes: • Occurrence of disease before 14 days • Drug side effects</td>
</tr>
<tr>
<td>Chahla et al., 2021</td>
<td>Personnel who perform patient care and administrative tasks (healthcare and non-healthcare personnel) n = 234</td>
<td>Ivermectin 12mg/tab PO every 7 days, + iota-carrageenan 6 oral sprays per day, for 4 weeks</td>
<td>No Ivermectin or carrageenan, only usual standard precautions and PPE</td>
<td>Primary outcome: • Prevention of COVID-19 (RT PCR confirmation) Secondary outcome: • Adverse events</td>
</tr>
</tbody>
</table>
## Appendix 2. GRADE Evidence Profile

<table>
<thead>
<tr>
<th>Study design</th>
<th>Risk of bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Consideration</th>
<th>Ivermectin</th>
<th>No Ivermectin</th>
<th>Relative (95% CI)</th>
<th>Absolute (95% CI)</th>
<th>Certainty</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of RT-PCR confirmed COVID-19 (Elgazzar 2021)</td>
<td>1 randomised trials</td>
<td>very serious</td>
<td>not serious</td>
<td>serious</td>
<td>serious</td>
<td>none</td>
<td>2/100 (2.0%)</td>
<td>10/100 (10.0%)</td>
<td>RR 0.2000 (0.045 to 0.8898)</td>
<td>80 fewer per 1,000 (from 98 fewer to 11 fewer)</td>
<td>✅ ◯ ◯ ◯</td>
</tr>
<tr>
<td>Development of RT-PCR Confirmed COVID-19 (Chahla 2021)</td>
<td>1 randomised trials</td>
<td>very serious</td>
<td>not serious</td>
<td>serious</td>
<td>not serious</td>
<td>none</td>
<td>4/117 (3.4%)</td>
<td>25/117 (21.4%)</td>
<td>RR 0.1600 (0.057 to 0.4455)</td>
<td>179 fewer per 1,000 (from 201 fewer to 118 fewer)</td>
<td>✅ ◯ ◯ ◯</td>
</tr>
<tr>
<td>Development of COVID-19 related symptoms (Shoumann 2021)</td>
<td>1 randomised trials</td>
<td>very serious</td>
<td>not serious</td>
<td>serious</td>
<td>not serious</td>
<td>none</td>
<td>15/203 (7.4%)</td>
<td>59/101 (58.4%)</td>
<td>RR 0.1265 (0.075 to 0.2115)</td>
<td>510 fewer per 1,000 (from 540 fewer to 461 fewer)</td>
<td>✅ ◯ ◯ ◯</td>
</tr>
</tbody>
</table>

CI: Confidence interval; RR: Risk ratio

### Explanations
a. Unclear allocation concealment, incomplete reporting of results (article was only a preprint), no data on breakdown of household contacts and healthcare workers

b. Indirect evidence for the general population

c. Wide confidence interval

d. The study by Shoumann demonstrated high risk of bias in terms of blinding, selective reporting and incomplete outcome data. Subjects recruited did not undergo baseline RT-PCR tests to confirm that they were indeed COVID negative. Most participants in both groups who were diagnosed to have COVID-19 infection also did not undergo confirmatory RT-PCR tests, and were only diagnosed based on presence of symptoms. The non-intervention group was also prematurely stopped due to the perceived high protective efficacy of ivermectin by the researchers.

e. Lack of blinding, allocation concealment, co-intervention bias
## Appendix 3. Table of Completed Unpublished Studies (no preprint available)

<table>
<thead>
<tr>
<th>Study</th>
<th>Population/Setting</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcomes</th>
<th>Status</th>
</tr>
</thead>
</table>
| A Preventive Treatment for Migrant Workers at High-risk of COVID-19 | Men residing in dormitory Ages 21-69 years 4257 participants Singapore | Arm 1: Hydroxychloroquine  
Arm 2: Ivermectin  
Arm 3: Zinc/Vit C  
Arm 4: Povidone-iodine throat spray  
Arm 5: Vitamin C | - | Primary: Laboratory-confirmed COVID-19  
Secondary: 1. Acute respiratory illness in treatment arms  
2. Febrile respiratory illness in treatment arms  
3. Rate of hospitalization for COVID-19 and non-COVID-19 related indications  
4. Rate of O2 supplementation  
5. Duration of O2 supplementation and mechanical ventilation  
6. Length of hospital stay  
7. Rate of laboratory-confirmed COVID-19  
8. Adverse events and serious adverse events  
9. Drug discontinuation due to adverse events | Completed, no available results  
Completion date: August 31, 2020 |
| Evaluation of prophylaxis induced by ivermectin in populations exposed to COVID-19 patients | Healthy individuals exposed directly and constantly with COVID-19 patients Ages 18-65 years Iran | Ivermectin | Placebo | Primary: 1. Percentage of patients in family members  
2. Duration of Illness  
3. Severity of Illness  
Secondary: 1. Considering the drug side effects  
2. IgA  
3. IgM  
4. IgG | Completed  
Completion date: December 30, 2020 |
### Appendix 3. Table of Ongoing Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Population/Setting</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcomes</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy of Nano-Ivermectin Impregnated Masks in Prevention of Covid-19 Among Healthy Contacts and Medical Staff</td>
<td>Health care personnel and family contact of confirmed COVID-19 cases Ages 18 years and older Estimated: 150 participants Egypt</td>
<td>Ivermectin mask</td>
<td>Ordinary Mask</td>
<td>Primary: 1. Number of persons who complain of any suspected symptoms (within 14 days after enrolment) 2. Number of persons who are diagnosed as COVID-19 patients (within 21 days of enrolment)</td>
<td>Recruiting Estimated Completion Date: February 28, 2021 (not yet updated in registry)</td>
</tr>
</tbody>
</table>
## Philippine COVID-19 Living Clinical Practice Guidelines

### Exploratory Ph I Trial of the Active IMP in Healthy Volunteers in Relation to COVID-19

- **Study Title:** Exploratory Ph I Trial of the Active IMP in Healthy Volunteers in Relation to COVID-19
- **NCT Number:** NCT04632706
- **Study Type:** Randomized Double-Blind, Placebo-controlled Trial
- **Objective:** Prevention and Treatment for COVID-19 associated severe

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Description</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Primary</th>
<th>Secondary</th>
<th>Status</th>
<th>Estimated Completion Date</th>
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</thead>
<tbody>
<tr>
<td>Exploratory Ph I Trial of the Active IMP in Healthy Volunteers in Relation to COVID-19</td>
<td>Healthy male with negative RT-PCR test for SARS-CoV 2; Ages 18-45 years; Estimated: 24 participants; United Kingdom</td>
<td>Ivermectin 50 mcg/kg, 75 mcg/kg, 100 mcg/kg doses</td>
<td>Placebo</td>
<td>Primary: 1. Maximum plasma concentration (Cmax) 2. Time to reach Cmax (Tmax) 3. Trough Plasma Concentration 4. Area under the plasma concentration-time curve from zero to 24 hrs 5. Area under the plasma concentration-time curve from zero to 48 hrs 6. Apparent Terminal Half-life</td>
<td>Secondary: 1. Number of participants with treatment emergent adverse events 2. Number of participants with abnormal ECG 3. Number of participants with abnormal clinical neurological exam 4. Number of participants with abnormal urine and/or blood test 5. Number of participants with abnormal physical exams</td>
<td>Recruiting</td>
<td>Estimated completion date: May 2021</td>
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<tr>
<td>Prevention and Treatment for COVID-19 associated severe</td>
<td>Cohort 1: Index case ≥ 5 years with confirmed COVID-19 mild</td>
<td>Ivermectin</td>
<td>Placebo</td>
<td>Primary: 1. Cohort 1 Index Case: Percentage of patients with COVID-19</td>
<td></td>
<td>Recruiting</td>
<td>Estimated completion</td>
</tr>
<tr>
<td>Study Title</td>
<td>Design</td>
<td>Interventions</td>
<td>Outcomes</td>
<td>Countries</td>
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<td>Estimated/Actual Completion Date</td>
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</table>
| Pneumonia in the Gambia (PaTS-COVID)                                      | Single-Blinded Randomized Trial                                         | Disease or moderate pneumonia - Household contacts                           | Cohort 2: Individuals with suspected or confirmed COVID-19 disease or moderate pneumonia  
|                                                                            |                                                                        | Ages ≥ 12 years with confirmed COVID-19                                       | Cohort 2: Individuals with suspected or confirmed COVID-19 disease or moderate pneumonia  
|                                                                            |                                                                        | Ages ≥ 5 years estimate: 1200 participants                                    | 2. Cohort 1 Household contacts: Percentage of HH members that get infected with COVID-19  
|                                                                            |                                                                        |                                                                             | 3. Cohort 2: Percentage of COVID-19 associated severe pneumonia patients    | Gambia        | date: July 2022                |                                  |
| Effectiveness and Safety of Ivermectin for the Prevention of COVID-19     | Randomized multi-center trial                                           | Health care worker, with negative COVID-19 serological antibody test          | Primary: Clinical development of COVID-19                                  | Colombia      | Not yet recruiting             | Estimated completion date:       |
| Infection in Colombian Health Personnel (IverprofCovid19)                 |                                                                        | Age ≥ 18 years estimate: 550 participants                                     | Secondary: 1. Seroconversion  
|                                                                            |                                                                        |                                                                             | 2. Hospitalization requirement  
|                                                                            |                                                                        |                                                                             | 3. ICU Requirement  
|                                                                            |                                                                        |                                                                             | 4. Safety of the intervention  | Colombia       |                               | December 16, 2020               |
| Prophylactic Ivermectin in COVID 19 Contacts                              |                                                                         | Healthy contacts of COVID-19 patients                                          | Primary: Episodes and severity of symptoms of respiratory tract infection  
|                                                                            |                                                                        | Ages 18-70 years                                                                | Secondary:                                               | India          | Not yet recruiting             |                                  |
### Ivermectin as COVID-19 Prophylaxis

**Philippine COVID-19 Living Clinical Practice Guidelines**

<table>
<thead>
<tr>
<th>Randomized Trial</th>
<th>Study Description</th>
<th>Treatment</th>
<th>Control</th>
<th>Primary</th>
<th>Secondary</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin in the prevention of COVID-19</td>
<td>Healthy volunteers with high chances of exposure to COVID-19 patients</td>
<td>Ivermectin</td>
<td>Placebo</td>
<td>Clinical development of COVID-19</td>
<td>Seroconversion, Hospitalization requirement, ICU Requirement, Safety of the intervention</td>
<td>Recruiting, Estimated completion date: July 2022</td>
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<tr>
<td>CTRI/2020/06/026232</td>
<td>Age ≥ 18 years, India</td>
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<tr>
<td>Randomized trial</td>
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<tr>
<td>Study of the effects of using ivermectin to prevent COVID-19 in an adult population in Brazil</td>
<td>Healthy volunteer, Ages ≥ 18 years, Brazil</td>
<td>Ivermectin</td>
<td>Placebo</td>
<td>COVID-19 case diagnosis</td>
<td>Clinical status of COVID-19, Incidence of severe COVID-19, Rate of adverse events, Hospitalization, Deaths</td>
<td>Recruiting, Estimated completion date: June 30, 2021</td>
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<td>ISRCTN90437126</td>
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<tr>
<td>Randomized trial</td>
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<tr>
<td>Randomized clinical trial of ivermectin for treatment and prophylaxis of COVID-19</td>
<td>Contacts of symptomatic COVID-19 patients, Ages 18-64 years, 229 participants, Spain</td>
<td>Ivermectin</td>
<td>Placebo</td>
<td>Incidence of secondary cases of COVID-19</td>
<td>Morbidity and mortality at 28 days, Analytical values at 0, 7, 12, 21 days</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>