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17 March 2021

Adrian O'Flynn

By email: fyi-request-14723-f507199c@requests.fyi.org.nz
Ref: H202101604

Dear Adrian O'Flynn

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 19 February 2021 regarding the use of ivermectin as a treatment for COVID-19.

Your questions and my responses are as follows.

> *Does the Ministry of Health stand by it's comments on 8 April 2020? If yes, why?*

Thank you for your inquiry. Your point is well taken that it is important to keep up to date on the current evidence of therapies used for the treatment of COVID-19. However, the Ministry's statement on 8 April 2020 (www.health.govt.nz/news-media/news-items/caution-about-laboratory-covid-19-report) is still in-line with the current evidence.

Evidence from high-quality randomised controlled trials is required to demonstrate the benefits and to assess the safety of therapies so it can be approved for a specific indication. To date, there are only a few small randomised clinical trials evaluating ivermectin as a therapy for COVID-19. The results are mixed with most studies showing no benefit. Generally, the quality of clinical evidence is low as the majority are preprint, non-peer-reviewed trials with small sample sizes.

> *Who in the Ministry of Health reviews the scientific studies on the efficacy of Ivermectin in the treatment of Covid-19? This could be part of a general body that looks at possible treatments for Covid-19. If there is no body, then why does the Ministry of Health not have such a body?*

The Science and Technical Advisory team in the COVID-19 Health System Response Directorate is constantly looking for and reviewing the evidence regarding effective therapies for COVID-19, including the use of ivermectin. It should be noted that Medsafe is the regulatory body responsible for recommendations on therapies in New Zealand, not the Ministry.

If there is a person/body, which studies has the person/body responsible for reviewing the efficacy of Ivermectin in the treatment of Covid-19 considered or reviewed on the efficacy of Ivermectin in the treatment of Covid-19 since the 8 April 2020? Please provide the list of studies and/or scientific papers that the person/body has reviewed.

The Science and Technical Advisory team have reviewed the evidence for the treatment of COVID-19 with ivermectin therapy. A copy of this review is attached as Appendix 1 to this letter.

Neither the National Institutes of Health (NIH) in the United States nor the World Health Organization (WHO) recommend ivermectin for the treatment of COVID-19. You may be interested in several ongoing reviews that can be found at:

- The NIH: www.covid19treatmentguidelines.nih.gov/antiviral-therapy/
- The NIH National Library of Medicine (PubMed): https://pubmed.ncbi.nlm.nih.gov/
- The WHO: www.who.int/publications/i/item/therapeutics-and-covid-19-living-guideline
- The British Medical Journal *'Drug treatments for covid-19: living systematic review and network meta-analysis, BMJ 2020; 370'*: www.doi.org/10.1136/bmj.m2980
- The United States Centers for Disease Control and Prevention: www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html

Has the person/body responsible for reviewing the efficacy of Ivermectin in the treatment of Covid-19 considered the research undertaken by: Frontline COVID-19 Critical Care Alliance; Dr. Andrew Hill of Liverpool University, and his meta-analysis on the efficacy of Ivermectin in the treatment of Covid-19; Dr. Tess Lawrie, Director of The Evidence-Based Medicine Consultancy Ltd, and her meta-analysis on the efficacy of Ivermectin in the treatment of Covid-19?

These pieces of work have been reviewed.

If the person/body responsible for reviewing the efficacy of Ivermectin in the treatment of Covid-19 has considered the studies and meta-analyses why does this person/body not consider Ivermectin an effective treatment in Covid-19? If the person/body responsible for reviewing the efficacy of Ivermectin in the treatment of Covid-19 has not considered the studies and meta-analyses will that person consider the studies and meta-analyses. If no, why? If yes, when will a statement either confirming or changing the Ministry of Health's position be issued?

Much of this evidence is based on observational data, which is prone to confounding and other biases, therefore it cannot be used as the basis for guidance for therapies. Some of the evidence is not peer-reviewed and is only available on social media channels or in preprint. This research includes some randomised clinical trial data, but those studies have mixed results, are often small studies and overall provide a low level of clinical evidence.

You may be interested in a response from Medsafe regarding ivermectin which is available at: www.health.govt.nz/system/files/documents/information-release/h202100482_15_feb_2021.pdf.

I trust this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Gill Hall
Group Manager, COVID-19 Science and Insights
COVID-19 Health System Response

Response to Request for Information

Key points

- In order for a therapy to be approved for a specific indication, evidence from high-quality randomized controlled trials are required to demonstrate benefit and begin to assess safety.
- There are few, small randomized clinical trials evaluating ivermectin as a therapy for COVID-19. Results are mixed, with most studies showing no benefit. Generally, the quality of evidence is low: the majority are preprint, non-peer-reviewed trials, with small sample sizes.
- There are two peer-reviewed clinical trial comparing ivermectin therapy to comparator, and both studies showed no mortality benefit for ivermectin[1, 2].
- In addition, there are several observational studies of ivermectin. One recent systematic review, retrieved 4 observational studies: 3 with comparator arms and one without a comparator group.[3] The review found a statistically significant effect on mortality and symptoms, but the quality of evidence was very low.
- There is no strong evidence to date of benefit for ivermectin as a therapy for COVID-19.

Objective

To summarize the evidence for the treatment of COVID-19 with ivermectin therapy

Background

Indications

In New Zealand, ivermectin is approved for treating intestinal strongyloidiasis (anguillulosis), microfilaraemia in patients with lymphatic filariasis caused by Wuchereria bancrofti, and human scabies after prior treatment has failed.[4] Elsewhere, ivermectin is used for the treatment of onchocerciasis (river blindness)

Safety

In general, ivermectin has a good safety profile. Side effects are related to the microfilarial density and most of them are mild and transient in nature.[4]

Mechanism of action (MOA)

Until recently, ivermectin was primarily an antiparasitic medicine. It works by binding to glutamate-gated chloride ion channels to alter chloride channel function; and by acting as a gamma-aminobutyric acid agonist in the parasite. This leads to parasite paralysis and death. In recent years, ivermectin has shown antiviral activity against a broad range of viruses in vitro. Ivermectin's MOA is inhibition of replication. The antiviral activity is purportedly due to the inhibition of importin (IMP) α/β Integrase which helps in the nuclear import and propagation of infection of RNA viruses. Based on this, researchers have proposed evaluating ivermectin as an add on therapy for COVID-19 treatment.

Methodology

The following search strategy was used:

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to February 01, 2021>, adapted for Embase, Scopus, Cochrane, Europe PMC for Preprints, Clinical Trials Databases

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1 Ivermectin/ or Ivermectin.mp. or ivomec.mp. or Stromectol.mp. or Soolantra.mp. or Sklice.mp. or Mectizan.mp.
2 (2019-ncov or ncov19 or ncov-19 or 2019-novel CoV or sars-cov2 or sars-cov-2 or sarscov2 or sarscov-2 or Sars-coronavirus2 or Sars-coronavirus-2 or SARS-like coronavirus* or coronavirus-19 or covid19 or covid-19 or covid 2019 or ((novel or new or nouveau) adj2 (CoV on nCoV or covid or coronavirus* or corona virus or Pandemi*2)) or ((covid or covid19 or covid-19) and pandemic*2) or (coronavirus* and pneumonia)).mp.
3 1 and 2
4 limit 3 to randomized controlled trial
5 3 and (trial* or random* or control*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
6 4 or 5

In addition, ClinicalTrials.gov was reviewed for any trials comparing ivermectin to control, that had reported results.

Evidence for effectiveness

Clinical trial evidence

This review evaluates results from nine clinical trials. Three of the RCTs were peer-reviewed[1, 2, 5], however they were too small to demonstrate significance clinical benefit. Two studies reported statistically significant differences between the ivermectin treatment and control arms. However, neither studies were peer-reviewed: one study the results were only available on ClinicaTrials.gov[6]; the other study reported a mortality benefit for ivermectin, but mortality was not a pre-specified outcome for the trial.[7]

Studies where ivermectin was compared to another active comparator that was itself an experimental therapy, rather than standard or care or placebo, were excluded. Studies evaluating ivermectin as a prophylaxis were not included. No studies demonstrated a pre-specified mortality benefit outcome. Results are summarized in Table 1.

- Hashim, et al.[8] compared the combination of ivermectin+doxycycline with standard care (SC). The did not find any statistically significant results. However, they reported in-hospital mortality of 2.9% and 8.6% in the ivermectin+doxycycline combination therapy and SOC groups, respectively. Disease progression was lower in the combination therapy group compared to SC (4.3% vs. 10%, respectively).
- Study NCT04523831[6] was an ivermectin+doxycycline combination study that evaluated only mild or moderate COVID patients, and therefore mortality was not a prespecified outcome. They reported a higher rate of clinical improvement within 7 days in the ivermectin+doxycycline group compared to comparator (60.7% vs 44.4%, respectively). They also found that fewer patients in the treatment arm than the SC arm took 12 days or more to improve (23% and 37.2%, respectively), and a lower rate of clinical deterioration (8.7% vs 17.85%, respectively). Results were statistically significant.
- SAINT trial[5] was a small phase 2 trial of N=24 patients, with the primary objective of assessing viral load in patients with mild and moderate COVID after one dose of ivermectin, compared to placebo. They found no statistically significant differences between the groups.

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- Shakhsi Niaee, et al.[9] reported a 6-arm trial with two comparator arms (SC, SC+placebo) and 4 treatment arms with different regimens of ivermectin. All patients received hydroxychloroquine 200mg/kg twice per day as part of SC. In-hospital mortality was 3.3% and 18.3% in the ivermectin therapy arms (combined) and comparator arms (combined), respectively, but the difference is not statistically significant. There was no evidence of benefit for the other outcomes (duration of hospital admission and low O2, fever, and tachypnea).
- Podder, et al.[10] was an open-label RCT that reported no differences between the ivermectin and comparator arms. Results are not peer-reviewed.
- Ravikirti, et al.[7] reported a mortality benefit for ivermectin (in-hospital mortality was 0% (0/55) in the ivermectin group and 6.9% (4/58) in the placebo group. However, mortality was not a pre-specified primary or secondary outcome. Results are not peer-reviewed.
- Both Charchar, et al. and Krolewiecki, et al. were small studies that did not report significant differences in prespecified outcomes.[2, 11]

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Table 1 Summary of randomised clinical trial data evaluating ivermectin against a control, as of 03 February 2021l

Trial name	Trial	Patients	Intervention	Outcome Measures/ Results	Location	Comment
Hashim et a, 2020, (preprint)[8] NCT04591600	RCT, combination therapy	Outpatient and inpatient groups with COVID-19 diagnosed using clinical, radiological and laboratory PCR testing.	IVM+DOXY: 2-3 days of 200 µg/kg IVM + 5-10 days DOXY + standard care (SC), N=70 Comparator: SC, N=70 SC included 5dexamethasone 6 mg/day or methylprednisolone 40mg twice per day, as needed	*Mortality*: IVM+DOXY: 2.9% (2/70) SC: 8.6% (6/70) P=0.16 *Disease progression:* IVM+DOXY: 4.3% (3/70) SC: 10% (7/70) P=0.19	Alkarkh Health Directorate-Baghdad, Iraq	Results were not significant, but ivermectin group tended to have greater benefit on mortality and disease progression. Results not peer-reviewed
NCT04523831, [6]preliminary results reported on ClinicalTrials.gov, not peer-reviewed	RCT, double-blind, combination therapy	Outpatient and inpatient groups with mild or moderate disease patients, diagnosed using PCR	IVM+DOXY: 6-12 mg IVM + 5 days DOXY + SC, N=183 Comparator: SC, N=180	*Mortality:* IVM+DOXY: 0% SC: 1.7% P-value not reported *Early clinical improvement <7 days* IVM+DOXY: 60.7% SC: 44.4% P<0.03 *Clinical improvement >12 days*: IVM+DOXY: 23% SC: 37.2% P<0.004 *Clinical deterioration:* IVM+DOXY: 8.7%	Dhaka Medical College, Bangladesh	Study of patients at low risk for severe COVID. IVM+DOXY group had higher rate of for clinical improvement within 7 days and lower rate of disease progression Results not peer-reviewed

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				SC: 17.8% P<0.013		
Ahmed et al 2021. International Journal of Infectious Diseases[1]	RCT, double-blind, 3 arm trial of monotherapy, combination therapy, and placebo.	Inpatient with COVID-19 diagnosed with physical exam and PCR	IVM monotherapy: Oral ivermectin alone (12 mg once daily for 5 days), N=22. IVM+DOXY: oral ivermectin in combination with doxycycline (12 mg ivermectin single dose and 200 mg doxycycline on day 1, followed by 100 mg every 12 h for the next 4 days), N=23 Comparator: SC+ Placebo, N=23	*Mortality:* 0 events in any arm *Remission of fever in 7 days* IVM: 100% IVM+DOXY: 94.1% Placebo: 84.2% *Remission of cough in 7 days* IVM: 38.9% IVM+DOXY: 36.8% Placebo: 60% *Hospital duration, mean days:* IVM: 9.6 IVM+DOXY: 10 Pb: 9.7 No statistically significant differences in any of the outcomes.	Dhaka, Bangladesh	No evidence for mortality benefit. Study too small to produce statistically significance. Mixed results when comparing treatment arms to comparator. Peer-reviewed.

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Chaccour et al, SAINT trial NCT04390022[5]	RCT, Double-blind Phase2/pilot study of N=24 patients to evaluate if ivermectin reduces nasal viral carriage	Patients diagnosed with COVID-19 in the emergency room with a positive PCR. Patients at low risk of progressing to severe disease: patients with serious comorbidities were excluded.	IVM: Single dose of 400 mcg/kg ivermectin, N=12 Comparator: placebo, N=12	*Symptoms*: IVM group reported fewer patient-days of symptoms overall, primarily driven by less anosmia/hyposmia and cough. No significant difference in the proportion of PCR positive patients, viral loads, or lower IgG titers post-treatment.	Universidad de Navarra, Spain	Small pilot study, no evidence of benefit.
Shakhsi Niaee et al 2020. Preprint.[9]	Phase 2 RCT, placebo-controlled 6 arm trial: SOC, SOC+placebo, and 4 arms were different regimens of IVM.	Adults over 18 with clinical symptoms suggestive of COVID-19. Mild to severe COVID-19 disease confirmed by CT scan or positive RT-PCR.	IVM arms (N=180 total): 1) single dose ivermectin (200mcg/Kg, 1 pill per day) +SC, N=30 2) three low interval doses of ivermectin (200, 200, 200 mcg/Kg, 3 pills in 1, 3 and 5 interval days) +SC, N=30 3) single dose ivermectin (400mcg/Kg, 2 pills per day) +SC, N=30 4) three high interval doses of ivermectin (400, 200, 200 mcg/Kg, 4 pills in 1, 3 and 5 interval days+SC, N=30 Comparator arms: 5) common regimen based on Iran health ministry (Hydroxychloroquine 200mg/kg twice per day), N=30	*Mortality:* IVM: 3.3% Comparator arms: 18.3% P-value not reported (not statistically significant) *Other outcomes:* Evidence of difference among all 6 treatment groups for duration of hospital stay and low O2, fever, and tachypnea, but no evidence of benefit for IVM over comparator groups for any of those outcomes. No statistically significant difference for any of the outcomes.	Qazvin science & technology park, Iran	All patients received hydroxychloroquine 200mg/kg twice per day as part of SC. The two comparator arms were combined, as were the 4 IVM arms.

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			6) placebo plus common regime, N=30			
Podder, et al.[10] Preprint	Open-label, RCT with ivermectin and SC comparator arms.	Patients aged 18 and over with mild to moderate COVID-19. Patients with known pre-existing hypersensitivity to Ivermectin, pregnant and lactating mothers, and patients taking other antimicrobials or hydroxychloroquine were excluded.	IVM: 200 micrograms/kg single dose+SC, N=32 Comparator: SC, N=30	No significant differences between the treatment and control arms for any outcomes, including recovery time, number of patients with negative RT-PCR on day 10.	Bangladesh	No significant differences between treatment and control groups. Small sample size.

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Ravikirti et al.[7] Preprint	RCT, placebo-controlled	Patients with mild to moderate COVID-19, aged 18 and over, no contraindications to ivermectin.	IVM: 12 mg on day 1 and day 2, N=55 Comparator: Placebo+SC, N=58	*Mortality*: IVM 0% (0/55) Placebo: 6.9% (4/58) No significant differences between the groups for any outcomes, i.e., negative RT-PCR on day 6, symptoms day 6, discharge status day 10, ICU admission, ventilation.	Bihar, India	Mortality benefit in the IVM arm, but mortality was not a prespecified outcome.
Charchar, et al.[2]	Open-label RCT	Adult patients (18-75) with mild disease only	IVM: 12mg day 1, 12 mg after 12 hours, and 12mg after 24 hours+SC, N=25 Comparator: SC, N=25	*Symptomatic at day 7:* IVM: 36% (9/25) Control: 40% (10/25) No significant difference	Lahore, India	No significant differences

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Krolewiecki, et al.[11] NCT004381884 Preprint	RCT	Adult patients with mild or moderate COVID-19	IVM: standard of care plus oral IVM at 0·6 mg/kg/day for 5 days, N=30 Comparator: standard of care, N=15	*Viral load reduction:* No significant difference Post-hoc difference comparing patients with high IVM plasma levels and controls	Argentina	No significant differences in prespecified outcomes.

SC=Standard of care; IVM=Ivermectin; DOXY=Doxycycline

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Observational studies

There have been several observational studies and systematic reviews reporting the outcomes for patients that received ivermectin as part of their therapy. Padhy et al[3] performed a recent systematic review of four observational studies, and found a statistically significant effect on mortality and symptoms, although the quality of evidence was very low. Another recent systematic review of twelve studies[12] (five retrospective cohort studies, six randomized clinical trials and one case series) reported that ivermectin was not associated with reduced mortality or differences in patient recovery. Both systematic reviews noted that the quality of evidence was very low.

Other reviews

A recent review by the New South Wales' Agency for Clinical Innovation concluded that there was insufficient evidence to support the use of ivermectin for prophylaxis or treatment of COVID-19.[13]

The US CDC issued current recommendations for clinicians regarding investigational therapeutics for patients with COVID-19, in conjunction with the US National Institutes of Health.[14, 15] Ivermectin is not a therapy that is recommended for treatment of COVID-19 at this time by the US NIH; specifically, with regard to anti-viral therapies, the US NIH found there was insufficient data for or against ivermectin as a therapy for COVID-19.[16]

Neither the US Food and Drug Administration (US FDA) nor the European Medicines Agency (EMA) has approved ivermectin for prevention or treatment for COVID-19.[17, 18]

The World Health Organization's guidelines on therapeutics for COVID-19 do not include ivermectin as a recommended therapy.[19]

Cochrane review

There are no completed reviews of therapies for COVID-19. A protocol for a Cochrane review has been published, but there is no expected date for publication of results.[20]

Conclusions

In order for a therapy to be approved for a specific indication, evidence from high-quality randomized controlled trials are required to demonstrate benefit and begin to assess safety.

There are few, small randomized clinical trials evaluating ivermectin as a therapy for COVID-19. Results are mixed, with most studies showing no benefit. Generally, the quality of evidence is low: the majority are preprint, non-peer-reviewed trials, with small sample sizes.

In addition, there are several observational studies of ivermectin. One recent systematic review, of 4 observational studies found a statistically significant effect on mortality and symptoms, but the quality of evidence was very low.

There is no strong evidence to date of benefit for ivermectin as a therapy for COVID-19.

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Next Steps

In the development of this work, the following parties have been consulted with:	
What are the implications and considerations of this advice on Te Tiriti o Waitangi and equity?	

Resources used:		
Ministry of Health Policies and Procedures	☐ Yes ☐ No	
External Health Scientific organisations	☐ Yes ☐ No	
Existing database of RFAs	☐ Yes ☐ No	
Internal MH Advice	☐ Yes ☐ No	
External Expert Advice	☐ Yes ☐ No	
Literature Review	☐ Yes ☐ No	

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