Healthcare workers' reasons for choosing between two different COVID-19 prophylaxis trials in an acute pandemic context: Results from an online survey

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Abstract

Background: In April 2020, two independent clinical trials (CT) to assess SARS-Cov-2 prophylaxis in healthcare workers were started in our Hospital: MeCOVID (melatonin vs placebo) and EPICOS (tenofovir disoproxil/emtricitabine vs hydroxychloroquine vs the combination of both vs placebo).

Objective: We aim to evaluate the motivations to participate and the reasons to choose one or another.

Methods: Both CTs were offered to personnel through the internal news bulletin. After the screening visit, all subjects were asked to answer a web-based survey.

Results: In the first month, 206 healthcare workers were screened and 160 randomized. Survey participation was quite high, 73.3%. The main motivation to participate was "to contribute to scientific knowledge" 53.0%, followed by "to avoid SARS-Cov-2 infection" and "the interest to be tested for SARS-CoV-2". We found differences between physicians and nurses in the expected personal benefits ($P<0.05$). The vast majority of the volunteers selected the MeCOVID study, the main reason was the fear of adverse reactions associated with treatments in EPICOS, 69.4%.

Conclusions: Healthcare workers´ motivations to participate in prophylaxis trials in a pandemic context appear to be driven mostly by their desire to contribute to science and getting some health benefits. Safety seems to weight way more than efficacy to choose between CTs.

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Healthcare workers' reasons for choosing between two different COVID-19 prophylaxis trials in an acute pandemic context: Results from an online survey

Abstract

Background: In April 2020, two independent clinical trials (CT) to assess SARS-CoV-2 prophylaxis in healthcare workers were started in our Hospital: MeCOVID (melatonin vs placebo) and EPICOS (tenofovir disoproxil/emtricitabine vs hydroxychloroquine vs the combination of both vs placebo).
Objective: We aim to evaluate the motivations to participate and the reasons to choose one or another.
Methods: Both CTs were offered to personnel through the internal news bulletin. After the screening visit, all subjects were asked to answer a web-based survey.
Results: In the first month, 206 healthcare workers were screened and 160 randomized. Survey participation was quite high, 73.3%. The main motivation to participate was "to contribute to scientific knowledge" 53.0%, followed by "to avoid SARS-CoV-2 infection" and "the interest to be tested for SARS-CoV-2". We found differences between physicians and nurses in the expected personal benefits (*P=.01*). The vast majority of volunteers selected the MeCOVID study, the main reason was the fear of adverse reactions associated with treatments in EPICOS, 69.4%.
Conclusions: Healthcare workers´ motivations to participate in prophylaxis trials in a pandemic

context appear to be driven mostly by their desire to contribute to science and to gain some health benefits. Safety seems to weight way more than efficacy when choosing between CTs.

Keywords: SARS-CoV-2; prophylaxis; healthcare workers; clinical trials; volunteers, online survey.

Introduction

Motivators for participating in clinical trials have been evaluated mainly in therapeutic and phase I studies. However, no much information is available on subject's motivators to participate in prophylaxis trials in the context of an epidemic, as the one we are currently experiencing during the COVID-19 pandemic, especially in western countries. In this setting, when several trials might compete in recruitment of patients in the same centre, reasons for choosing one or another can be very relevant.

Currently, there is no approved pre-exposure prophylaxis therapy for SARS-CoV-2 infection, but a number of clinical trials (CT) have been initiated in Europe and US, most of them including hydroxychloroquine as prophylactic agent [1-5] (EudraCT-2020-001565-37; EudraCT-2020-001536-98; NCT04352946; NCT04354870; NCT04328467).

As of April 21st, 2020, two independent CT to assess SARS-CoV-2 infection prophylaxis in healthcare worker were started at the Clinical Trials Unit in La Paz University Hospital. The MeCOVID study compares melatonin and placebo (EudraCT- 2020-001530-35) and the EPICOS study is a four-arm CT including tenofovir disoproxil/emtricitabine, hydroxychloroquine, the combination of both and placebo (EudraCT-2020-001385-11).

We aim to evaluate the motivations of the healthcare workers of our hospital to participate in COVID-19 prophylaxis trials and the reasons to select one trial over another of the two trials we are carrying out in our centre.

Methods

Both CTs were offered to personnel of our Hospital through the internal news bulletin. All potential participants received the information about both CT and had the opportunity to have any questions answered before choosing between the studies. Healthcare workers' choice was not influenced by the investigator team.

Participants were screened to the chosen trial. In both CTs they were tested to SARS-CoV-2 infection using a serologic rapid test (Orient Gene® or Wondfo®). All screened subjects were asked to answer a web-based survey after the screening visit.

The questionnaire consisted of nine questions about demographic data, professional position and working site, insight into COVID-19, motivation to participate, reasons to choose one trial over the other and treatment expectations (see Multimedia Appendix 1).

The survey was assembled using Google Forms® platform. An invitation letter containing a link to the questionnaire was distributed via email to all screened volunteers. There were no reminders for non-responders. Participants' answers are anonymous and confidential according to Google's privacy policy.

Descriptive statistics were calculated for all variables, with percentages being reported. The Shapiro–Wilk test was used to contrast if age was normally distributed in our population. We rejected the null hypothesis in the test for normality ($P<.001$) concluding that age shows a non-normal distribution.

Statistical analyses were performed using R software (V 3.6.3). To assess for significant differences between age and position Mann–Whitney U test was applied. Significant differences between sex and position were assessed using Chi Square. Significant differences in responses between physicians and nurses were tested using Fisher's exact test.

Results

In the first month of recruitment 206 healthcare workers were screened and 160 were randomized (156 in MeCOVID and 4 in EPICOS). Volunteers chose in which trial they wanted to participate, the vast majority selected the MeCOVID study (n=202, 98.0%). Table 1 shows the disposition of survey outcomes in the sampling frame.

Table 2 shows the main data and results obtained from the survey by position (physician vs nurses vs others).

Data show 37.1% of the participants in the survey (n=56) considered to have expert-high knowledge of COVID-19, 69.6% of them were physicians (n=39) , 28.6% nurses (n=16) and 1.8% others (n=1) . The main motivation to participate was “to contribute to scientific knowledge” (n=80, 53.0%), followed by “to avoid SARS-CoV-2 infection” (n=33, 21.9%) and “the interest to be tested for SARS-CoV-2 by a serologic Rapid Test” (n=28, 18.5%).

In relation to the expected personal benefits, we found differences between physicians and nurses: the main expected benefit among physicians was to get access to SARS-CoV-2rapid tests (54.6%, n=18) while among nurses was to prevent SARS-CoV-2 infection (62.5%, n=20), being these differences statistically significant (*P=.01*) (See Table S2 in Multimedia Appendix 3).

Among the 147 subjects in MeCOVID, the main reason to choose this clinical trial was “the fear to present any toxicity related to EPICOS treatments (n=102, 69.4%)” while the main reason for participants to select EPICOS was “the belief that hydroxychloroquine and tenofovir/emtricitabina might be more effective than melatonin to prevent SARS-CoV-2 infection” (n=2, 50%).

Again there were significant differences between physicians and nurses in the reasons for choosing MeCOVID. Thus, ADRs associated to EPICOS drugs was mentioned by 53 physicians (85.5%) vs 49 (63.6%) nurses. Conversely, the higher efficacy of melatonin was mentioned by 17 nurses (22.1%) vs only 2 physicians (3.2%) and the use of melatonin as a sleep aid also by 17 nurses (22.1%) vs only 6 (9.7%) physicians (*P<.001*).

Expectations about MeCOVID results were mainly that melatonin would be efficacious and safe (n=84, 57.1%) followed by a 29.9% of the participants believing that melatonin would not be efficacious but at least will not produce adverse reactions (n=44). Most of the participants in EPICOS trial expected the treatment to be efficacious but to produce some adverse reaction (n=3, 75%).

Table 1. Disposition of outcomes in the sampling frame

Elegible participants (number of healthcare workers screened)	**206**
Returned questionnaire, n(%)	**151 (73.3%)**
Complete	142 (68.9%)
Partial or break-off with sufficient information [a]	9 (4.4%)
No Returned Questionnaire (Non-response), n(%)	**55 (26.7%)**
Logged on to survey, did not complete any items [b]	16 (7.8%)
Nothing ever returned [c]	29 (14.1%)
Invitation returned undelivered [d]	10 (4.8%)

[a] Access to the survey is registered and almost all of the questions answered (maximum 2 questions not answered).

[b] Access to the survey has been registered, but no questions have been answered.

[c] Remaining sample (those left after taking out “returned questionnaires”, “logged on to survey, did not complete any items” and “Invitation returned undelivered”.

[d] E-mail invitation was returned as undeliverable. Delivery has failed to the recipient due to incorrect, outdated or out of space email address.

Table 2. Main results of the survey in participants (data obtained from returned questionnaires), by position (physician vs nurses vs others)

	Physicians (n=64)	Nurses [b] (n=79)	Others [c] (n=8)	*P* [d]
No. with data (%)	**64 (100)**	**79 (100)**	**8 (100)**	
Sex, No. male (%)	27 (42.2)	9 (11.4)	1 (12.5)	.001
Age, median (IQR), years	41 (31-51)	37 (29-46)	46 (31-56)	.14
Knowledge, n(%)				
Expert -High	39 (60.9)	16 (20.2)	1 (12.5)	.001
Basic	25 (39.1)	55 (69.6)	7 (87.5)	
Some	0	7 (8.9)	0	
None Knowledge	0	1 (1.3)	0	
Working Site, n(%)				
Emergency Department	8 (12.5)	16 (20.3)	6 (75.0)	.01
Intensive Care Units	4 (6.3)	18 (22.8)	1 (12.5)	
Hospitalization wards	31 (48.4)	26 (32.9)	1 (12.5)	
External Offices/Other	21 (32.8)	19 (24.0)	0	
Main motivators, n(%)				
Scientific knowledge	31 (48.5)	42 (53.2)	7 (87.5)	.03
To prevent SARS-CoV-2 infection	13 (20.3)	20 (25.3)	0	
To have access to a SARS-CoV-2 rapid test	18 (28.1)	9 (11.4)	1 (12.5)	
Other	2 (3.1)	8 (10.1)	0	
MeCOVID participants, n	**62**	**77**	**8**	
Reason to participate in MeCOVID, n(%) (multiple answer question)				
ADRs Risk with EPICOS drugs	53 (85.5)	49 (63.6)	0	<.001
Sleep aid	6 (9.7)	17 (22.1)	1 (12.5)	
More efficacy	2 (3.2)	17 (22.1)	6 (75.0)	
CI EPICOS	1 (1.6)	4 (5.2)	0	
NR	4 (6.5)	1 (1.3)	1 (12.5)	
Expectations about MeCOVID trial, n(%)				
Efficacy+Safe	26 (42.0)	50 (64.9)	8 (100)	.13
Efficacy+ADRs	2 (3.2)	14 (18.2)	0	
No efficacy but without ADRs	31 (50.0)	13 (16.9)	0	
No efficacy + ADRs	1 (1.6)	0	0	
NR	2 (3.2)	0	0	

[a] Abbreviations: ADR, Adverse Drug Reaction; CI, contraindication; NR: Not reported

[b] "Nurses" includes nurse practitioners (n=54) and nursing assistants (n=25).

[c] "Others" includes laboratory technicians (n=2) and ancillary personnel (n=6)

[d] *P* values refer to differences between "physicians" and "nurses". "Others" have been excluded for the analysis due to the small sample.

Discussion

Prevention of SARS-CoV-2 transmission among healthcare workers is a key action in the management of the COVID-19 outbreak. Although reliable numbers on COVID-19-infected

healthcare workers lack, reports in Spain show a 20%, about a 10% in Italy and US, a 6% in Holland and 3.8% in China [6]. Drug prophylaxis is one of the measures proposed to prevent SARS-CoV-2 infection among healthcare workers and it is a priority to obtain strong evidence on this intervention.
We have evaluated the motivations of healthcare workers of our hospital to participate in prophylaxis trials and the reasons to choose one of the two studies offered given their different characteristics. Survey participation is quite high (151, 73.3%) and complete filling of the questionnaire was almost 70%. In our opinion the reason for this is the use of an "on line" survey easy to answer (only about 5' to complete).
Empirical studies have found that altruism and self-interest are the two primary motivations for enrolment in non-payed clinical trials. This is so in a wide variety of clinical situations, including participation in prophylaxis and vaccines trials, and in different geographical areas [7,10].
As far as we know this is the first study of this type made in an acute pandemic context. In this situation, the motivations of healthcare workers, who are well aware of the severity and complications of COVID-19, to participate in the trials were similar to that reported in other clinical situations: to contribute to science (n=80, 53%) and personal benefits (n=71, 47.0%), without differences between physicians and nurses. However, the expected personal benefits were significantly different between physicians and nurses, physicians were more interested in having access to SARS-CoV-2 rapid tests while nurses expected to prevent SARS-CoV-2 infection. This mix of motivating factors has been also reported in subjects participating in HIV prophylaxis trials and Ebola vaccine trials [11-14].
Regarding the reasons of subjects to decide between both trials, the most important was the fear of adverse reactions associated with treatments in EPICOS, and thus, two out of three volunteers selected MECOVID due to this reason. It seems that volunteer's perceived participation in MECOVID as less risky (choosing this trial despite one in three subjects do not expect efficacy). The reasons to choose MeCOVID were also significantly different between physicians and nurses, physicians were more concerned about ADRs.

Strengths and Limitations

Although the sample size in our study is large, and survey participation was high, our methodology is not exempt from limitations. There are some sources of bias in our study: selection bias, given that it was conducted in a single centre, and also we have a poor representation of EPICOS participants (n=4). However, as noted in the manuscript, one of our goals was to evaluate motivations of healthcare workers to participate in COVID-19 prophylaxis trials, which is independent of the trial chosen. A great number of physicians and nurses participated in the survey, which enabled us to compare responses in both groups. Another limitation of this study is that we cannot precisely measure the reception of the survey by mail. To be conservative, in order to estimate survey participation, we have included in the denominator all those subjects we tried to reach.

Conclusions

According to our data, healthcare workers motivations to participate in prophylaxis trials in a pandemic context appear to be driven mostly by their desire to contribute to science and to get some health benefit. When several studies are offered, safety weights way more than efficacy for candidates to choose between them. The majority of participants chose the study for safety reasons, selecting the one perceived as less risky, even if they consider it less efficacious.

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Author Contributions: Conceptualization, AMB, AJC, JRA and IGG; methodology, IGG, JF and ER.; formal analysis, AMB, AJC and IGG.; investigation, LDG, ARM, LMS, JMV, ESM and JJG; data

curation, IGG; writing—original draft preparation, AMB and IGG.; writing—review and editing, AJC and JRA. All authors have read and agreed to the published version of the manuscript.
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Conflicts of Interest

None declared.

Abbreviations

ADR: Adverse Drug Reaction
CI: contraindication
CT: Clinical trial
JMIR: Journal of Medical Internet Research
NR: Not reported
RCT: randomized controlled trial

Multimedia Appendix 1

Survey: Original Spanish version and English translation

Multimedia Appendix 2

Table S1. Main motivations to participate in the trials classified as to contribute to science and personal benefits, subgrouped by physician vs nurses.

Multimedia Appendix 3

Table S2. Personal benefits to participate in the trials subgrouped by physician vs nurses.

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Supplementary Files

Multimedia Appendixes

Survey for volunteers participating in clinical trials for COVID-19 porphylaxis.
URL: https://asset.jmir.pub/assets/eabe990917493cec1a5ef153879eab36.pdf

Table S1. Main motivations to participate in the trials classified as to contribute to science and personal benefits, subgrouped by physician vs nurses.
URL: https://asset.jmir.pub/assets/01660e6b265559b51988a9abaff08628.doc

Personal benefits to participate in the trials subgrouped by physician vs nurses.
URL: https://asset.jmir.pub/assets/800df3a7ffb61bc19637235b1a2f82b2.doc