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The possible beneficial role of the regular use of potent mouthwash solutions in the treatment of COVID-19

Submission date
03/10/2020

Recruitment status
No longer recruiting

Registration date
05/10/2020

Overall study status
Completed

Last Edited
16/12/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
Some over-the-counter mouthwash solutions have been shown to kill bacteria and viruses in laboratory studies. This study aims to test this effect in people with COVID-19.

Who can participate?
Patients aged 18 and older who have tested positive for COVID-19

What does the study involve?
Participants will be randomly allocated to receive a strong mouthwash solution, to be used 3 times a day for 2 weeks, or treatment as usual.

What are the possible benefits and risks of participating?
Possible benefits include faster recovery and fewer secondary bacterial infections in the upper

respiratory tract. Possible risks include mouth irritation, especially if there are mouth ulcers or sensitivity to the components, as well as digestive system irritation if hydrogen peroxide is ingested in quantities larger than the total daily recommended dose.

Where is the study run from?
1. Hazm Mebaireek General Hospital (Qatar)
2. Communicable Disease Center - Hamad Medical Corporation (Qatar)

When is the study starting and how long is it expected to run for?
April 2020 to November 2020

Who is funding the study?
Hamad Medical Corporation (Qatar)

Who is the main contact?
Dr Khalid Mukhtar
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

MRC 05-106

Study information

Scientific Title
Effect of regular use of hydrogen peroxide and chlorhexidine gluconate mixed solution for mouth wash and gargles on the COVID-19 recovery rate: a randomized controlled trial

Study objectives
The development and progression of the disease following exposure to SARS-CoV-2 is affected by the microbial communities in the oral cavity; proposing a "complicit agent" hypothesis, either a single microbial agent effect (presence of complicit or absence of a protective) or the state of dysbiosis in general. Meanwhile, game theory and evolutionary biology suggests that inhibiting cooperation - reciprocal altruism - between two organisms can negatively affect their survival. The researchers propose that regular use of potent mouthwash can improve the disease course, as the strain of the continual reduction in the microbial load is likely to inhibit their cooperation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/08/2020, Hamad Medical Corporations' Medical Research Center IRB (Medical Research Center, Hamad Medical City, Doha, Qatar; +974 (0)5554 6316; IRB@hamad.qa), ref: MRC 05-106

Study design
Interventional randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
New admissions (24 hrs) will be screened for eligibility. Recruited subjects will be randomly allocated to either the study or control group.

Study group: Potent disinfectant solution (10 ml Chlorhexidine gluconate 0.2% + 5 ml of hydrogen peroxide 6%) will be provided three times daily for 2 weeks, to be used for mouth rinse and gargles (>30 sec) and to avoid eating or drinking for at least 5 more minutes

Control group: treatment as usual

Intervention Type
Other

Primary outcome measure
1. Recovery assessed using clinical improvement along with a negative COVID RT-PCR test at 5 and 15 days of starting treatment
2. Changes in the CT-values of COVID-19 RT-PCR inconclusive test at 5 and 15 days of starting treatment

Secondary outcome measures
1. Clinical symptoms assessed using the Sore Throat Assessment Tool for the first 5 days
2. COVID progression (ICU intubation vs discharge or transfer to quarantine) recorded by reviewing medical records within the study duration
3. Hospital stay measured using (days) at discharge; or at the end of study for those remained admitted
4. Disposition type (discharged/death) measured using hospital records entries at the time of discharge, or reported mortality during hospital stay

Overall study start date
30/04/2020

Completion date
20/11/2020

Eligibility

Key inclusion criteria
1. Age 18 years and older
2. COVID-19 reported via positive PCR within 2 weeks of admission
3. Conscious, oriented and can comprehend the study purpose and risks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

100

Total final enrolment
100

Key exclusion criteria
1. Pregnancy (females)
2. Intubated (at the time of recruitment) or had any reported cognitive impairment that can prevent proper comprehension of the study or communicating side effects
3. Contra-indication for mouth wash use, e.g. reported allergies to the solution constituents, recent facial/head injuries, maxillofacial conditions

Date of first enrolment
08/09/2020

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
Qatar

Study participating centre
Hazm Mebaireek General Hospital
Hamad Medical Corporation
Doha Industrial Area (west)
Doha
Qatar
-

Study participating centre
Communicable Disease Center - Hamad Medical Corporation
Hamad Medical City
Doha
Qatar
-

Sponsor information

Organisation
Hamad Medical Corporation

Sponsor details
Medical Research Center
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Sponsor type
Industry

Website
https://www.hamad.qa/EN/Pages/default.aspx

ROR
https://ror.org/02zwb6n98

Funder(s)

Funder type
Industry

Funder Name
Hamad Medical Corporation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
Kmukhter@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	non-peer-reviewed results in preprint	30/11/2020	16/03/2021	No	No

Basic results	04/05/2021	05/05/2021	No	No