ISRCTN95933274 https://doi.org/10.1186/ISRCTN95933274

Efficacy of mouth-rinses in reducing SARS CoV-2 viral load in the saliva of COVID-19 positive patients

Submission date
07/09/2020

Recruitment status
No longer recruiting

Registration date
09/09/2020

Overall study status
Completed

Last Edited
16/12/2020

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 April 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.
The aim of this study is to evaluate the effectiveness of commonly used commercial mouth-rinses (Betadine Gargle and Mouthwash, Pearlie white Chlor-rinse and Colgate Plax mouthwash) to reduce SARS-CoV-2 viral level in the saliva of COVID-19 positive patients. This study will provide evidence on the use of mouth rinses in reducing the viral load in the saliva of the COVID-19 patients and thereby help in reducing transmission of COVID-19.

Who can participate?
Patients with laboratory-confirmed diagnosis of COVID-19

What does the study involve?
Participants are randomly allocated to receive either Betadine Gargle and Mouthwash, Pearlie white Chlor-rinse, Colgate Plax mouthwash or water (control group). They are asked to provide saliva samples by spitting, then they are asked to rinse their mouth with mouth-rinse or water. Saliva samples are collected again at 5 minutes, 3 hours and 6 hours after using the mouth-rinse.

What are the possible benefits and risks of participating?
There is no known benefit to the participant. However, their participation may add to the medical knowledge about the effectiveness of mouthwashes against SARS-CoV-2, as well as the use of mouthwashes to reduce the spread of COVID-19 through saliva. There is no potential risk to participants from saliva collection methods as it is a non-invasive method.

Where is the study run from?
Singapore General Hospital (Singapore)

When is the study starting and how long is it expected to run for?
April 2020 to June 2021

Who is funding the study?
National Dental Center Singapore (Singapore)

Who is the main contact?
A/Prof C.J. Seneviratne
jaya.seneviratne@ndcs.com.sg

Contact information

Type(s)
Scientific

Contact name
Dr Jaya Seneviratne

Contact details
5 Second Hospital Ave
Singapore
Singapore
168938
+65 (0)65767141
jaya.seneviratne@ndcs.com.sg

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
329/2020

Study information

Scientific Title
Evaluating the comparative efficacy of virucidal mouth-rinses in reducing SARS-CoV-2 viral load in saliva as a pre-procedural prophylactic strategy in healthcare settings

Study objectives
1. To comparatively evaluate the viral load of SARS CoV-2 in saliva before and 5 minutes after application of povidone-iodine (PI), chlorhexidine gluconate (CHX) and cetylpyridinium chloride (CPC) mouth-rinses in COVID-19 positive patients compared to water rinse.
2. To assess the duration of effectiveness of PVP-I, CHX and CPC mouthwashes in reducing the viral load of SARS-CoV-2 in COVID-19 positive patients at 3 h and 6 h time intervals compared to water rinse.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/06/2020, Centralised Institutional Review Board (168 Jalan Bukit Merah, #06-08 Tower 3 Connection One,
Singapore, 150168; +65 (0)6323 7515; irb@singhealth.com.sg), ref: 2020/2537

Study design
Single-centre interventional clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
The subjects are randomly allocated to three mouth-rinse groups, namely povidone-iodine (PI), chlorhexidine gluconate (CHX) and cetylpyridinium chloride (CPC) and water control group.
Allocation: using Robust Randomization App (RRApp) using block randomization technique
Masking: single-blind

Prior to saliva collection, patients are asked to refrain from eating, drinking, or performing oral hygiene procedures for at least 30 min. Three milliliters of saliva is collected by passive drool technique from all the enrolled COVID-19 patients at four timepoints. Firstly, a baseline saliva

sample is collected prior to the intervention of the mouth-rinse. Immediately after this, patients are requested to rinse their mouth with the allocated mouth-rinse for 30 seconds. Commercial mouth-rinses are prepared at the dilution and dosage recommended by respective manufacturers. In brief, in the PI group 5 ml of PI mouthwash (commercially available as Betadine Gargle and Mouthwash 10 mg) diluted with 5 ml of water (0.5%) is used whereas in the CHX group, 15 mL of undiluted CHX mouthwash (commercially available as Pearly White Chlor-Rinse, 0.2% w/v) is used. In the CPC group and water control groups, 20 ml of 0.075% CPC (commercially available as Colgate Plax mouthwash) and 15 ml sterile water are used, respectively. Three milliliters of saliva is collected again from all subjects 5 minutes after the use of mouth-rinse. In order to evaluate the duration of the efficacy of mouth-rinses, salivary samples are collected at the 3 h and 6 h post-rinsing.

Intervention Type
Other

Primary outcome measure
Salivary CT values of SARS CoV-2 measured using reverse-transcription polymerase chain reaction (RT-PCR) at baseline, 5 min, 3 h and 6 h

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
15/04/2020

Completion date
16/06/2021

Eligibility

Key inclusion criteria
Laboratory-confirmed COVID-19-positive patients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
68

Total final enrolment
36

Key exclusion criteria

1. History of allergy to PI, CPC or CHX and its relevant excipients
2. All forms of thyroid disease or current radioactive iodine treatment
3. Lithium therapy
4. Known pregnancy
5. Renal failure

Date of first enrolment
30/06/2020

Date of final enrolment
16/06/2021

Locations

Countries of recruitment
Singapore

Study participating centre
Singapore General Hospital
Outram Rd
Singapore
Singapore
169608

Sponsor information

Organisation
National Dental Centre of Singapore

Sponsor details
5 Second Hospital Ave
Singapore
Singapore
168938
+65 (0)63275063
research@ndcs.com.sg

Sponsor type
Research organisation

Website
http://www.ndcs.com.sg/Pages/Home.aspx

ROR

https://ror.org/03w6pea42

Funder(s)

Funder type
Research organisation

Funder Name
National Dental Centre of Singapore

Results and Publications

Publication and dissemination plan
The protocol will be included in future publications. The results of the study will be published as soon as a reasonable conclusion is made from the study in a high-impact peer-reviewed journal.

Intention to publish date
16/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from A/Prof.C.J. Seneviratne (jaya.seneviratne@ndcs.com.sg).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2021	16/12/2020	Yes	No