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Effects of chlorhexidine gluconate and povidone-iodine mouthwash on viral load in patients infected with SARS-CoV-2

Submission date
28/04/2025

Recruitment status
No longer recruiting

Registration date
02/05/2025

Overall study status
Completed

Last Edited
30/04/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at how different mouthwashes affect COVID-19 patients. COVID-19 is caused by the SARS-CoV-2 virus, which can change and become more contagious. Some mouthwashes might help reduce the virus in the mouth. The study aims to see if two types of mouthwash (0.2% chlorhexidine gluconate and 1% povidone-iodine) can lower the amount of virus in patients with COVID-19.

Who can participate?
The study includes 45 patients who have COVID-19.

What does the study involve?
Participants are divided into three groups. One group uses 0.2% chlorhexidine gluconate mouthwash, another uses 1% povidone-iodine mouthwash, and the third group uses mineral water as a control. They gargle with their assigned solution three times a day for five days. Researchers test the amount of virus in their mouth at the start, on day three, and on day five.

What are the possible benefits and risks of participating?
The main benefit is potentially reducing the amount of virus in the mouth, which might help with recovery. Risks are minimal but could include mild irritation from the mouthwash.

Where is the study run from?
The study is conducted by the Oral and Maxillofacial Surgery Department at the Faculty of Dentistry, Universitas Indonesia.

When is the study starting and how long is it expected to run for?
August 2022 to December 2022

Who is funding the study?
The study is funded by Universitas Indonesia through the PUTI Grant

Who is the main contact?
Prof Lilies Dwi Sulistyani, liliesdwi_s@yahoo.co.id

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
73/KEPK-RSUPP/08/2022

Study information

Scientific Title
Effects of chlorhexidine gluconate and povidone-iodine mouthwash on cycle threshold values in patients infected with SARS-CoV-2

Acronym
Effects of mouthwash on SARS-CoV-2

Study objectives
Chlorhexidine gluconate and povidone-iodine mouthwash increase cycle threshold values in patients infected with SARS-CoV-2

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/08/2022, Health Ethics Committee of Persahabatan Central General Hospital (Persahabatan Raya No.1, East Jakarta, 13230, Indonesia; +62 214891708; info@rsuppersahabatan.co.id), ref: 73/KEPK-RSUPP/08/2022

Primary study design

Interventional

Study design
Single-blinded non-randomized controlled clinical trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Reduction of SARS CoV-2 viral load

Interventions
This single-blind, nonrandomized controlled clinical trial comprised 45 patients who were divided into three intervention groups: 0.2% chlorhexidine gluconate (MINOSEP®) mouthwash group (n = 15); 1% povidone iodine (BETADINE®) mouthwash group (n = 15), and mineral water (AQUATM, DANONE-Indonesia) control group (n = 15). The mouthwash was repackaged in a 125 ml bottles. Each subject received two bottles (total, 225 ml of mouthwash) and 15 ml measuring cups.

Patients who met the inclusion criteria and were being treated at the oral and maxillofacial surgery clinic underwent RT-PCR examination. Collection of sample material for RT-PCR was carried out by a trained personnel in the microbiology laboratory at Persahabatan Hospital, and there was no specific time for sample collection. The patients were instructed to gargle with 15 ml of the mouthwash (30s in the oral cavity and 30 s in the back of the throat) three times a day for 5 days. After gargling, they were asked to rinse their mouth with 15 ml of water. Observations were carried out via video call after every gargle. RT-PCR examinations were performed to obtain the CT values at initial diagnosis and on days 3 and 5. All sample materials for RT-PCR were taken from the oropharynx. The Vitro Master Diagnostica® (IVD Reagent MAD-003941M, Spain) reagent was used in RT-PCR. The use of this reagent in all samples will allow CT values to be measured as well as S gene targets to be identified. Samples without the S gene will be categorized as SGTF, whereas samples with the S gene will be categorized as non-SGTF.

Intervention Type
Other

Primary outcome(s)
The CT values were estimated from the RT-PCR results at initial diagnosis, and on days 3 and 5

Key secondary outcome(s)
Cycle Threshold value of RT-PCR on day 3 and 5

Completion date
31/12/2022

Eligibility

Key inclusion criteria

1. SARS-CoV-2-positive patients based on RT-PCR results over the past <3 days
2. An RT-PCR CT value of ≤30
3. Outpatients with mild or no symptoms
4. Aged 20 to 50 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Patients with comorbidities
2. History of allergy to povidone iodine mouthwash and chlorhexidine gluconate
3. Pregnant females
4. Those who were not willing to participate in the study

Date of first enrolment
01/09/2022

Date of final enrolment
30/12/2022

Locations

Countries of recruitment
Indonesia

Study participating centre
Persahabatan Hospital
Persahabatan Raya No.1

East Jakarta
Indonesia
13230

Sponsor information

Organisation
University of Indonesia

ROR
https://ror.org/0116zj450

Funder(s)

Funder type
University/education

Funder Name
Hibah PUTI Universitas Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to patients confidentiality

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/04/2025	No	Yes
Protocol file			30/04/2025	No	No
Statistical Analysis Plan			30/04/2025	No	No