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Does mouthrinsing and gargling with povidone iodine and hydrogen peroxide reduce the number of SARS-CoV-2 viruses in patients with no and mild symptoms?

Submission date
18/01/2022

Recruitment status
No longer recruiting

Registration date
03/02/2022

Overall study status
Completed

Last Edited
20/12/2022

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
Coronavirus disease 2019 (COVID-19) can spread rapidly. During surgical procedures in the mouth, the risk of transmitting SARS-CoV-2 virus is high. The American Dental Association (ADA) and Centers for Disease Control and Prevention (CDC) recommend mouthrinsing with 1.5% hydrogen peroxide or 0.2% povidone iodine to reduce the risk of transmission by reducing the number of viruses in mouth and throat. This study aims to analyse if mouthrinsing and gargling with 1% povidone iodine, 0.5% povidone iodine, 3% hydrogen peroxide, 1.5% hydrogen peroxide and water will make any difference to the number of viruses.

Who can participate?
Adults 19 - 60 years old confirmed positive of SARS-CoV-2, diagnosed for less than three days at Persahabatan Central General Hospital during 1st July – 30th September 2021 with no or mild symptoms.

What does the study involve?
Participants were given mouthrinsing and gargling education through video conference, and mouthrinse that had been repackaged. Participants would need to perform mouthrinsing for 30 seconds in the mouth and gargling and 30 seconds in the back of the throat with 15 mL of mouthrinse 3 times a day for 5 days. The mouthrinsing and gargling activity was carried out in the self-isolation room of each research subject by using video conference. Participants were subjected to RT-PCR test on day 1, day 3 and day 5 after the mouthrinsing and gargling intervention.

What are the possible benefits and risks of participating?
The mouthrinsing and gargling procedures with povidone iodine or hydrogen peroxide were likely to benefit participants by reducing the numbers of viruses in the upper respiratory tract.

Furthermore, this study allows future benefits in reducing SARS-CoV-2 transmission during oral and maxillofacial surgery if the mouthrinsing and gargling procedures are recommended and implemented.

Where is the study run from?
The study was run by Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Universitas Indonesia, and took place Persahabatan Central General Hospital (Indonesia)

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Lilies Dwi Sulistyani, lilies.dwi@ui.ac.id

Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
The evaluation of povidone iodine and hydrogen peroxide mouthrinsing and gargling on CT value of SARS-CoV-2: a randomized controlled trial in asymptomatic and mild symptomatic patients

Study objectives

There is an effect of mouthrinsing and gargling with 1% and 0.5% povidone iodine, as well as 3% and 1.5% hydrogen peroxide on the CT value of RT-PCR SARS-CoV-2.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/06/2021, Persahabatan Central General Hospital (Jl. Persahabatan Raya No.1, RT.16 /RW.13, Rawamangun, Kec. Pulo Gadung, Kota Jakarta Timur, DKI Jakarta 13230 Indonesia; +62 (021) 22472222; info@rsuppersahabatan.co.id), ref: 68.A.1/KEPK-RSUPP/11/2021

Study design
Interventional single centre single blind randomized parallel trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Research subjects were given mouthrinsing and gargling protocol education through video conference and given mouthrinse that had been repackaged. The 1% povidone iodine group rinsed with BETADINE® Mouthwash and Gargle solution. The 3% hydrogen peroxide group rinsed with a solution from OneMed™. The group of 0.5% povidone iodine and 1.5% hydrogen peroxide rinsed with a diluted solution of 1% iodine povidone BETADINE® Mouthwash and Gargle and 3% hydrogen peroxide OneMed™ added with sterile distilled water with the formula Volume1 x Concentration1=Volume2 x Concentration2.
There were two intervention groups and one control group:
- Intervention 1: 1% povidone iodine
- Intervention 2: 0.5% povidone iodine
- Intervention 3: 3% hydrogen peroxide
- Intervention 4: 1.5% hydrogen peroxide
- Control: mineral water

Research subjects performed mouthrinsing for 30 seconds in the oral cavity and gargling and 30 seconds in the back of the throat with 15 mL of mouthrinse 3 times a day for 5 days. The mouthrinsing and gargling activity was carried out in the self-isolation room of each research subject by using video conference.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1% povidone iodine BETADINE®, 3% hydrogen peroxide OneMed™

Primary outcome(s)
Viral load measured using CT value of the RT-PCR examination on day 1, day 3 and day 5 after the mouthrinsing and gargling intervention

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/10/2021

Eligibility

Key inclusion criteria
1. Patients of Persahabatan Central General Hospital, (COVID-19 national referral centre)
2. Patients infected with SARS-CoV-2 and identified through RT-PCR with positive results at Persahabatan Central General Hospital during 1st July – 30th September 2021 with CT values ≤ 30
3. Asymptomatic patients or with mild symptoms
4. Patients being diagnosed with COVID-19 for less than three days
5. Aged 19 - 60 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
69

Key exclusion criteria
1. Patients not willing to be research subjects
2. Patients with comorbid and thyroid diseases
3. Pregnant patients
4. Patients routinely consumed lithium drugs
5. Patients undergoing radioactive iodine treatment
6. Patients allergic to povidone iodine and hydrogen peroxide

Date of first enrolment
01/07/2021

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Indonesia

Study participating centre
Persahabatan Central General Hospital
Persahabatan Raya No.1, RT.16/RW.13, Rawamangun, Pulo Gadung
East Jakarta
Indonesia
13230

Sponsor information

Organisation
Universitas Indonesia

Organisation
Persahabatan Central General Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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 the confidentiality of the patient's data policy from Persahabatan Central General Hospital.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2022	20/12/2022	Yes	No