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

Submission date
12/04/2021

Recruitment status
No longer recruiting

Registration date
30/04/2021

Overall study status
Completed

Last Edited
04/05/2021

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The purpose of this study is to evaluate the efficacy of commonly used commercial mouth-rinses (Betadine Gargle and Mouthwash, Oxyfresh Pro Formula mouthwash, Pepsodent Active Defense 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?
Subjects with laboratory-confirmed diagnosis of COVID-19 can participate in the study.

What does the study involve?
Subjects are randomised to receive either Betadine Gargle and Mouthwash, Oxyfresh Pro Formula mouthwash, Pepsodent Active Defense mouthwash or water (control group). They are asked to provide saliva samples by spitting method. Then, subjects are asked to rinse their mouth with mouth-rinse or water. The saliva sample is collected again at 5 min, 3 h and 6 h post-application of mouth-rinse.

What are the possible benefits and risks of participating?
There is no known benefit to the subject from participation in this study. However, their participation may add to the medical knowledge about the efficacy 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?
The study is run from YARSI Hospital (Internal Medicine Department Clinic) (Indonesia)

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

Who is funding the study?
Faculty of Dentistry Trisakti University (Indonesia)

Who is the main contact?
Dr. drg. Armelia Sari Widyarman, armeliasari@trisakti.ac.id

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
2021

Study information

Scientific Title
Efficacy of commercial mouth-rinses on SARS-CoV-2 viral load in saliva: a randomized control trial in Indonesia

Study objectives
PVI-I, CPC, and $NaClO_2$-based mouth rinses are effective against reducing SARS-CoV-2 viral load in the saliva compared to a control water rinse and the effect will last for 6 hours.

Objectives:
1. To comparatively evaluate the viral load of SARS-CoV-2 in saliva pre- and post-5-minute application of PVP-I, CPC and $NaClO_2$-based mouth-rinses in COVID-19 positive patients.
2. To assess the duration of efficacy of PVP-I, CPC and NaClO2-based mouth-rinses in reducing SARS-CoV-2 load in COVID-19 positive patients by the collection of saliva at 3 h and 6 h post-application of mouth-rinses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/03/2021, Institutional Review Board of Faculty of Dentistry, Trisakti University (Jl. Kyai Tapa No.1, RT.5 / RW.9, Tomang, Grogol Petamburan, West Jakarta City, Special Capital Region of Jakarta 11440, Jakarta, Indonesia; +628161908945; komisietikfkg@trisakti.ac.id), ref: 001/Dosen/KEPK/FKG/03/2021

Study design
Single-center single blind interventional randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Reducing the transmission of SARS CoV-2 virus in saliva of COVID-19 patients in Indonesia.

Interventions
The enrolled patients are randomized using Robust Randomization App (RRApp) using a block randomization technique and are allocated to four groups accordingly— PI, $NaClO_2$, CPC and water control group.

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 the passive drool technique from all the enrolled COVID-19 patients at four time points.

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 1%) diluted with 5 ml of water (0.5%) is used whereas in $NaClO_2$ group, 15 ml of undiluted $NaClO_2$ mouthwash (commercially available as Oxyfresh Pro Formula) is used. In the CPC group and water control groups, 20 ml of CPC (commercially available as Pepsodent Active Defense mouthwash) and 15 ml sterile water is used, respectively. Three milliliters of saliva is collected again from all subjects five 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
Supplement

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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
25/03/2021

Completion date
20/10/2021

Eligibility

Key inclusion criteria
Laboratory-confirmed COVID-19 positive patients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
68

Key exclusion criteria
1. History of allergy to PI, $NaClO_2$, CPC 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
10/05/2021

Date of final enrolment
10/06/2021

Locations

Countries of recruitment
Indonesia

Study participating centre
Internal Medicine Department Clinic YARSI Hospital
Jl. Letjend Suprapto No.Kav 13
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Cempaka Putih Timur
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Central Jakarta City
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Sponsor information

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Trisakti University

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Sponsor type
University/education

Website
http://trisakti.ac.id/fkg

ROR
https://ror.org/019fnr381

Funder(s)

Funder type
University/education

Funder Name
Universitas Trisakti

Alternative Name(s)
Trisakti University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

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

Intention to publish date
31/05/2022

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 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			04/05/2021	No	Yes