A Clinical Trial of Gargling Agents in Reducing Intraoral Viral Load in COVID-19 Patients (COVID-19)

ClinicalTrials.gov Identifier: NCT04341688

Recruitment Status : Not yet recruiting
First Posted : April 10, 2020
Last Update Posted : April 10, 2020

See Contacts and Locations

Sponsor:
Aga Khan University

Collaborator:
University of Karachi

Information provided by (Responsible Party):
Farhan Raza Khan, BDS, MS, FCPS, Aga Khan University

Study Description

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Brief Summary:

Pakistan is a resource restraint country, it's not possible to carry out coronavirus testing at mass scale. Owing to the aerosol producing nature of the dental profession, carrying out dental work on asymptomatic patients carrying coronavirus puts the entire dental team at a great risk of not only acquiring the infection but also transmitting it to the others.

Identifying an antiviral gargle that could substantially reduce the colonies of COVID-19 residing in mouth and oro-pharynx is likely to reduce the viral load. This topical therapy is speculated to substantially reduce the transmission of infection in micro-aerosol generated in the dental practice. Such topical anti-viral therapy could also help to improve the overall symptoms of the patient.

Condition or disease	Intervention/treatment	Phase
Intraoral Viral Load in Covid-19 Patients	Drug: Gargle/Mouthwash	Not Applicable

Detailed Description:

It will be a double blind-randomized controlled trial annexed with a laboratory based study. Clinical trial will be carried out at the Aga Khan University Hospital (AKUH), Karachi, Pakistan. Patients will be inducted from the pool of known patients (laboratory confirmed COVID-19 participants) already admitted at AKUH. Molecular and immunological testing will be done at the Juma laboratory of AKUH. The intervention drugs (Povidone-Iodine, Hydrogen Peroxide and Normal Saline will be obtained from the AKUH distribution department and/ or AKUH pharmacy. The Neem extract will be compounded at the Chemistry department, University of Karachi/ HEJ institute of Organic Chemistry, University of Karachi.

It will be a pilot study, so will need just 20 patients. There will be four groups. Group A (n=5) patients on 10 ml gargle of 0.2% Povidone-Iodine for 20-30 seconds, twice daily for 5 days. Group B (n=5) patients will be subjected to 10 ml gargle of 1% Hydrogen peroxide for 20-30 seconds, twice daily for 5 days. Group C will comprise of (n=5) subjects on 10ml gargle of Neem extract based mouth rinse for 20-30 seconds, twice daily for 5 days. Group D (n=5) patient will use normal saline gargle for a similar time period.

Data collection: The baseline oral swab will be taken from the tonsillar pillars on day one before initiating the gargles by trained dentist. The end-point oral swab will be taken on day 5, just after using the prescribed gargle. Patient will be provided a hood so that they themselves don't generate aerosol in the immediate vicinity while carrying out the gargling.

Repeated measures ANOVA will be used to compare the reduction in intra-oral viral loads and the change in inflammatory biomarkers in the four study groups. A p-value of <0.05 will be taken as statistically significant.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	5 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	A double blind-randomized controlled trial followed by laboratory based analysis. Four parallel groups of participants using antiviral gargles.
Masking:	Triple (Participant, Care Provider, Outcomes Assessor)
Masking Description:	Identical colored and shaped bottles containing four different study drugs
Primary Purpose:	Supportive Care
Official Title:	A Double Blind, Randomized Controlled Trial of Three Gargling Agents in Reducing Intraoral Viral Load in Subjects With Laboratory Confirmed Coronavirus Disease (COVID-19)
Estimated Study Start Date :	July 1, 2020
Estimated Primary Completion Date :	December 31, 2020
Estimated Study Completion Date :	March 31, 2021

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Povidone-Iodine 0.2% (BETADINE®) 0.2% Povidone-Iodine (BETADINE®) 10 ml gargle of for 20-30 seconds, twice daily for 5 days.	Drug: Gargle/Mouthwash There will be four groups. Group A (n=5) patients on 10 ml gargle of 0.2% Povidone-Iodine for 20-30 seconds, twice daily for 5 days. Group B (n=5) patients will be subjected to 10 ml gargle of 1% Hydrogen peroxide for 20-30 seconds, twice daily for 5 days. Group C will comprise of (n=5) subjects on 10ml gargle of Neem extract based solution for 20-30 seconds, twice daily for 5 days. Group D (n=5) patient will use normal saline gargle for a similar time period. Other Names: • Gargling agent • Mouthrinse
Experimental: Hydrogen peroxide 1% (ActiveOxy) ActiveOxy (% Hydrogen peroxide) 10 ml gargle of for 20-30 seconds, twice daily for 5 days.	Drug: Gargle/Mouthwash There will be four groups. Group A (n=5) patients on 10 ml gargle of 0.2% Povidone-Iodine for 20-30 seconds, twice daily for 5 days. Group B (n=5) patients will be subjected to 10 ml gargle of 1% Hydrogen peroxide for 20-30 seconds, twice daily for 5 days. Group C will comprise of (n=5) subjects on 10ml gargle of Neem extract based solution for 20-30 seconds, twice daily for 5 days. Group D (n=5) patient will use normal saline gargle for a similar time period. Other Names: • Gargling agent • Mouthrinse
Active Comparator: Neem extract (Azadirachta indicia) Azadirachta indicia will be prepared by chemistry lab. 10ml gargle for 20-30 seconds, twice daily for 5 days.	Drug: Gargle/Mouthwash There will be four groups. Group A (n=5) patients on 10 ml gargle of 0.2% Povidone-Iodine for 20-30 seconds, twice daily for 5 days. Group B (n=5) patients will be subjected to 10 ml gargle of 1% Hydrogen peroxide for 20-30 seconds, twice daily for 5 days. Group C will comprise of (n=5) subjects on 10ml gargle of Neem extract based solution for 20-30 seconds, twice daily for 5 days. Group D (n=5) patient will use normal saline gargle for a similar time period. Other Names: • Gargling agent • Mouthrinse
Active Comparator: Normal saline (0.9%NaCl) 10ml gargle of Normal saline Normal saline (0.9%NaCl) for 20-30 seconds, twice daily for 5 days.	Drug: Gargle/Mouthwash There will be four groups. Group A (n=5) patients on 10 ml gargle of 0.2% Povidone-Iodine for 20-30 seconds, twice daily for 5 days. Group B (n=5) patients will be subjected to 10 ml gargle of 1% Hydrogen peroxide for 20-30 seconds, twice daily for 5 days. Group C will comprise of (n=5) subjects on 10ml gargle of Neem extract based solution for 20-30 seconds, twice daily for 5 days. Group D (n=5) patient will use normal saline gargle for a similar time period. Other Names: • Gargling agent • Mouthrinse

Outcome Measures

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Primary Outcome Measures :

1. Intraoral viral load [Time Frame: Five days of using gargles]

   Intraoral viral load as deciphered by RT-PCR

Secondary Outcome Measures :

1. Salivary cytokine profile [Time Frame: Five days of using gargles]

   Salivary cytokine profiles of IL-2, IL-4, IL-6, IL-10, TNF-α, IFN-γ and IL-17.

Eligibility Criteria

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Information from the National Library of Medicine

NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 65 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- The inclusion criteria are laboratory confirmed Covid-19 positive male or female subjects in the age range of 18-70 years, already admitted in the hospital.

Exclusion Criteria:

- Edentulous patients, patients with low Glasgow coma score, intubated, immune-compromised, history of radiotherapy or chemotherapy will be excluded. Patients with known pre-existing chronic mucosal lesions such as lichen planus will also be excluded.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04341688***

Contacts

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Sponsors and Collaborators

Aga Khan University

University of Karachi

Investigators

Principal Investigator: Syed MR Kazmi, FCPS Aga Khan University

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Additional Information:

Burden of disease in COVID-19 pandemic Recommendation on elective and cosmetic dental procedures by ADA

Publications:

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Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Farhan Raza Khan, BDS, MS, FCPS, Aga Khan University:

Covid-19;
coronavirus disease
povidone
hydrogen peroxide
neem extracts
topical therapy
gargle

Additional relevant MeSH terms:

Povidone-Iodine
Hydrogen Peroxide
Povidone
Anti-Infective Agents, Local
Anti-Infective Agents
Plasma Substitutes
Blood Substitutes