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only one reference on povidine; concentration too low

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

ClinicalTrials.gov Identifier: NCT04341688

Recruitment Status : Not yet recruiting
First Posted : April 10, 2020
Last Update Posted : July 20, 2021

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. Simple cost effective intervention against the present pandemic is highly desirable.

For patients: Identifying an antiviral gargle that could substantially reduce the colonies of COVID-19 residing in mouth and oro-naso-pharynx is likely to reduce the viral load. Such reduction in the viral load through surface debridement could aid the effective immune response in improving the overall symptoms of the patients.

For dentists: This study is important because the nature of the dental profession involves aerosol production, 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. Antiviral gargles could be used by dentist and their auxiliaries as prophylaxis.

For physicians and nurses: The risk of morbidity and mortality is high among physicians and nurses involved in the screening and management of Covid-19 patients. Globally, over 215 physicians and surgeons have died while taking care of Covid-19 patients. The cause of death is attributed to high exposure of viral load. The antiviral gargles and nasal lavage can decrease the fatalities among doctors and nurses.

Thus, patients, physicians, nurses and dentists, all could be benefited with this findings of this study.

Condition or disease	Intervention/treatment	Phase
Covid-19	Drug: Gargle/Mouthwash	Not Applicable

Show detailed description

Study Design

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Study Type :

Interventional (Clinical Trial)

Estimated Enrollment :

50 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Intervention Model Description:

A quadruple blind randomized controlled trial followed by laboratory based analysis. Six parallel groups of participants using various gargles and nasal lavage.

Masking:

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Masking Description:

Identical colored and shaped bottles containing different study drugs. This will be provided by the pharmacy services of the university hospital.

Primary Purpose:

Supportive Care

Official Title:

A Double Blind, Randomized Controlled Pilot Trial of Gargling Agents in Reducing Intraoral Viral Load Among Laboratory Confirmed COVID-19 Patients: GARGLES STUDY

Estimated Study Start Date :

December 1, 2021

Estimated Primary Completion Date :

June 30, 2022

Estimated Study Completion Date :

July 31, 2022

Arms and Interventions

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Arm	Intervention/treatment

Arm	Intervention/treatment
Experimental: Povidone-Iodine 0.2% (BETADINE®) 0.2% Povidone-Iodine (BETADINE®) 10 ml gargle and nasal lavage for 20-30 seconds, thrice daily for 6 days.	Drug: Gargle/Mouthwash There will be 50 patients in six study groups. Group A (n=10) patients on 10 ml gargle and nasal lavage using 0.2% Povidone-Iodine (Betadiene®) for 20-30 seconds, thrice daily for 6 days. Group B (n=10) patients will be subjected to 10 ml gargle and nasal lavage using 1% Hydrogen peroxide (ActiveOxy®) for 20-30 seconds, thrice daily for 6 days. Group C will comprised of (n=10) subjects on 10ml gargle and nasal lavage using Neem extract solution (Azardirachta indica) formulated locally) for 20-30 seconds, thrice daily for 6 days. Group D (n=10) patients will use 2% hypertonic saline (Plabottle®) gargle and nasal lavage for a similar time period. Group E (n=10) will serve as positive controls. These will be given simple distilled water gargles and nasal lavage for 20-30 seconds, thrice daily for six days Whereas Group F (n=5) will comprise of negative controls, who will not use any gargles or nasal lavage during study period. Other Names: • Gargling agent • Mouthrinse

Arm	Intervention/treatment
Experimental: Hydrogen peroxide 1% (ActiveOxy) ActiveOxy (1% Hydrogen peroxide) 10 ml gargle and nasal lavage for 20-30 seconds, thrice daily for 6 days.	Drug: Gargle/Mouthwash There will be 50 patients in six study groups. Group A (n=10) patients on 10 ml gargle and nasal lavage using 0.2% Povidone-Iodine (Betadiene®) for 20-30 seconds, thrice daily for 6 days. Group B (n=10) patients will be subjected to 10 ml gargle and nasal lavage using 1% Hydrogen peroxide (ActiveOxy®) for 20-30 seconds, thrice daily for 6 days. Group C will comprised of (n=10) subjects on 10ml gargle and nasal lavage using Neem extract solution (Azardirachta indica) formulated locally) for 20-30 seconds, thrice daily for 6 days. Group D (n=10) patients will use 2% hypertonic saline (Plabottle®) gargle and nasal lavage for a similar time period. Group E (n=10) will serve as positive controls. These will be given simple distilled water gargles and nasal lavage for 20-30 seconds, thrice daily for six days Whereas Group F (n=5) will comprise of negative controls, who will not use any gargles or nasal lavage during study period. Other Names: • Gargling agent • Mouthrinse

Arm	Intervention/treatment
Active Comparator: Neem extract (Azadirachta indicia) Neem extract (Azadirachta indicia) gargle will be prepared by chemistry laboratory. patients will do 10ml gargle and nasal lavage for 20-30 seconds, thrice daily for 6 days.	Drug: Gargle/Mouthwash There will be 50 patients in six study groups. Group A (n=10) patients on 10 ml gargle and nasal lavage using 0.2% Povidone-Iodine (Betadiene®) for 20-30 seconds, thrice daily for 6 days. Group B (n=10) patients will be subjected to 10 ml gargle and nasal lavage using 1% Hydrogen peroxide (ActiveOxy®) for 20-30 seconds, thrice daily for 6 days. Group C will comprised of (n=10) subjects on 10ml gargle and nasal lavage using Neem extract solution (Azardirachta indica) formulated locally) for 20-30 seconds, thrice daily for 6 days. Group D (n=10) patients will use 2% hypertonic saline (Plabottle®) gargle and nasal lavage for a similar time period. Group E (n=10) will serve as positive controls. These will be given simple distilled water gargles and nasal lavage for 20-30 seconds, thrice daily for six days Whereas Group F (n=5) will comprise of negative controls, who will not use any gargles or nasal lavage during study period. Other Names: • Gargling agent • Mouthrinse

Arm	Intervention/treatment
Active Comparator: Hypertonic saline (2%NaCl) 10 ml gargle and nasal lavage using Hypertonic saline for 20-30 seconds, thrice daily for 6 days.	Drug: Gargle/Mouthwash There will be 50 patients in six study groups. Group A (n=10) patients on 10 ml gargle and nasal lavage using 0.2% Povidone-Iodine (Betadiene®) for 20-30 seconds, thrice daily for 6 days. Group B (n=10) patients will be subjected to 10 ml gargle and nasal lavage using 1% Hydrogen peroxide (ActiveOxy®) for 20-30 seconds, thrice daily for 6 days. Group C will comprised of (n=10) subjects on 10ml gargle and nasal lavage using Neem extract solution (Azardirachta indica) formulated locally) for 20-30 seconds, thrice daily for 6 days. Group D (n=10) patients will use 2% hypertonic saline (Plabottle®) gargle and nasal lavage for a similar time period. Group E (n=10) will serve as positive controls. These will be given simple distilled water gargles and nasal lavage for 20-30 seconds, thrice daily for six days Whereas Group F (n=5) will comprise of negative controls, who will not use any gargles or nasal lavage during study period. Other Names: • Gargling agent • Mouthrinse

Arm	Intervention/treatment
Placebo Comparator: Positive controls 10 ml gargle and nasal lavage using distilled water for 20-30 seconds, thrice daily for 6 days.	Drug: Gargle/Mouthwash There will be 50 patients in six study groups. Group A (n=10) patients on 10 ml gargle and nasal lavage using 0.2% Povidone-Iodine (Betadiene®) for 20-30 seconds, thrice daily for 6 days. Group B (n=10) patients will be subjected to 10 ml gargle and nasal lavage using 1% Hydrogen peroxide (ActiveOxy®) for 20-30 seconds, thrice daily for 6 days. Group C will comprised of (n=10) subjects on 10ml gargle and nasal lavage using Neem extract solution (Azardirachta indica) formulated locally) for 20-30 seconds, thrice daily for 6 days. Group D (n=10) patients will use 2% hypertonic saline (Plabottle®) gargle and nasal lavage for a similar time period. Group E (n=10) will serve as positive controls. These will be given simple distilled water gargles and nasal lavage for 20-30 seconds, thrice daily for six days Whereas Group F (n=5) will comprise of negative controls, who will not use any gargles or nasal lavage during study 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

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 18-65 years, within seven days of the onset of mild to moderate symptoms of viral infection, 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

Study Director: Syed MR Kazmi, FCPS Aga Khan University

More Information

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Additional Information:

Burden of disease in COVID-19 pandemic

Recommendation on elective and cosmetic dental procedures by ADA

Report on mortality of doctors and nurses combating corona virus pandemic

Data of Covid-19 patients in Pakistan

Publications:

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Burton MJ, Clarkson JE, Goulao B, Glenny AM, McBain AJ, Schilder AG, Webster KE, Worthington HV. Antimicrobial mouthwashes (gargling) and nasal sprays administered to patients with suspected or confirmed COVID-19 infection to improve patient outcomes and to protect healthcare workers treating them. Cochrane Database Syst Rev. 2020 Sep 16;9:CD013627. doi: 10.1002/14651858.CD013627.pub2.

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Responsible Party:

Farhan Raza Khan, BDS, MS, FCPS, Associate Professor, Aga Khan University

ClinicalTrials.gov Identifier:

NCT04341688 History of Changes

Other Study ID Numbers:

2020-Sur-ERC-4926

First Posted:

April 10, 2020 Key Record Dates

Last Update Posted:

July 20, 2021

Last Verified:

July 2021

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