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Measurement of the effect of mouthwash against COVID-19

Submission date
12/10/2020

Recruitment status
No longer recruiting

Registration date
09/11/2020

Overall study status
Completed

Last Edited
24/02/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
Salivary spit from the mouth and throat of coronavirus patients contains a lot of viruses in early infection. The spread of virus by contaminated saliva is a major risk for healthcare workers caring for these patients. Coronaviruses are surrounded by a “fatty” coating, which can be damaged by agents like hand gels and soaps, which is why regular hand washing is recommended to kill the virus and prevent the spread of the disease. These disinfectants cannot be swallowed, but studies have shown that several mouthwashes are able to kill viruses similar to coronavirus in the mouth and throat. Laboratory tests have indicated that certain components in mouthwashes are able to affect the coronavirus “coat”. Doctors need to know whether this will work in patients. This study aims to determine whether a single use of a mouthwash reduces the amount of virus in the mouth for up to 1 hour.

Who can participate?
Patients aged 18 and over who have tested positive for COVID-19 in the last 14 days

What does the study involve?
Participants are randomly allocated to one of three mouthwashes or a salt-water (control)

mouthwash. Theywill be asked to “spit” a sample of saliva into a pot at the start of the study. The clinician will then give patients one of the three mouthwashes (or salt water) to rinse in their mouth for 30 seconds. Patients will then spit out a sample of their saliva straight after rinsing, and after 15, 30 and 60 minutes. Samples will be taken to the lab to test how much virus it contains. Personal details will not be used and the saliva samples will be disposed of and destroyed after testing according to HTA regulations.

What are the possible benefits and risks of participating?
This study will not benefit patients directly or treat their coronavirus infection. This study is carried out to see if a mouthwash can reduce the risk of healthcare staff catching the disease. In one of the mouthwashes, there is a small risk of sensitivity to iodine (<1:1,000 individuals), which would give a burning sensation in the mouth.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
May 2020 to December 2020

Who is funding the study?
Venture Life (UK)

Who is the main contact?
Prof. David Thomas
thomasdw2@cardiff.ac.uk

Contact information

Type(s)
Public

Contact name
Prof David Thomas

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285247

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 285247

Study information

Scientific Title
Measurement of mouthwash anti-viral activity against COVID-19 (MOMA)

Acronym
MOMA

Study objectives
The single administration of mouthwashes may effectively reduce the viral load in the oral cavity for up to 1 hour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/7/20, South Central - Berkshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048310; berkshireb.rec@hra.nhs.uk), REC ref: 20/SC/0275

Study design
Four-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

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

Interventions
The study consists of a single treatment with no follow-up. Participants will be assigned to one of the four arms using a balanced randomisation scheme: Dentyl Mouthwash (Cetylperidium chloride 0.05% [v/v]); povidone-iodine (PVP-I 0.5% [v/v]); Ultradex (Cetylperidium chloride 0.1% [v/v]) or Normasol (sterile saline 0.9% [v/v]). The three test (active) agents will all be used according to their current marketing approval. Baseline saliva will be collected before the participant rinses their mouth with 10 ml of one of the three active mouthwashes or saline mouthwash, depending on allocation.

Infectious virus in salivary samples will be quantitated by performing serial dilutions in DMEM /FBS, and inoculating Vero E6 monolayers for 1 hour, then overlaying with 2% Avicel. After 3 days, Avicel will be removed, and plaques enumerated. Plaques will be stained with anti-spike (S2) antibody to confirm the identity of the isolated virus by immunofluorescence. Viral genomes will also be extracted from saliva and quantitated by RT-qPCR, using established primer sets.

Intervention Type
Other

Primary outcome measure
Viral load of SARS CoV-2 measured by in vitro culture and confirmed by RT-qPCR at 30 minutes

Secondary outcome measures
Viral load of SARS CoV-2 measured by in vitro culture and confirmed by RT-qPCR at baseline and then after 1, 15 and 60 minutes

Overall study start date
20/05/2020

Completion date
27/12/2020

Eligibility

Key inclusion criteria
Eligible patients will be approached and recruited from COVID in-patient wards within Cardiff and Vale University Health Board, Betsi Cadwaladr University Health Board, University Hospitals Bristol NHS Foundation Trust and Cwm Taf Morganwg University Health Board. Only patients who are deemed well enough and able to provide informed consent by their local clinical teams will be approached to take part in the study. Specific inclusion criteria are:
1. Adults aged ≥18 years
2. With positive SARS-CoV-2 carriage by RT-PCR within 14 days
3. Capable of using the mouthwash required by the trial
4. Capacity and capability to give informed consent to take part in the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
104

Total final enrolment
78

Key exclusion criteria
1. Known or suspected intolerance or hypersensitivity to povidone-iodine or other study materials (or closely related compounds) or any of their stated ingredients
2. Known pregnancy, currently breastfeeding or women of childbearing age without effective contraception
3. Current requirement for invasive or non-invasive ventilation; or planned within next 6 hours
4. Known dermatitis herpetiformis (Duhring's disease)
5. Inability to communicate in English or read English

Date of first enrolment
20/09/2020

Date of final enrolment
27/12/2020

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Cardiff and Vale UHB
Heath Park
Cardiff
United Kingdom
CF14 4XY

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Bristol Royal infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
Cardiff University

Sponsor details
Research and Innovation Services
Mackenzie House
Newport Road
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Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Industry

Funder Name
Venture Life

Results and Publications

Publication and dissemination plan
Planned publication in a high impact journal. The impact of this work may be significant in managing patients and there is a genuine desire to see and employ the results of the study (if positive) in the NHS and Welsh Assembly Government. Once the data is analysed, if positive, the results will initially be disseminated via the Chief Dental and Chief Medical Officers and submitted for publication with minimum delay.

Intention to publish date
01/02/2021

Individual participant data (IPD) sharing plan
Data will be available on request via communication with the PI Prof. David Thomas (thomasdw2@cardiff.ac.uk). The data will include the patient number in the study, mouthwash given and viral load in saliva at baseline and at each timepoint after administration of the mouthwash. No other data is recorded and the data is anonymised. The patients have given consent for the data to be stored.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2.1	05/10/2020	09/11/2020	No	No
Preprint results		17/02/2022	18/02/2022	No	No
Basic results		24/02/2022	24/02/2022	No	No
HRA research summary			28/06/2023	No	No