

# Measurement of the effect of mouthwash against COVID-19

<b>Submission date</b> 12/10/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/02/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> 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. They will 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

### ORCID ID

<http://orcid.org/0000-0001-7319-5820>

### Contact details

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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: Dentyll 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  $\geq 18$  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 (Duhning'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  
Cardiff  
Wales  
United Kingdom  
CF24 0DE  
+44 (0)2920874000  
resgov@cf.ac.uk

**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?
<a href="#">Protocol file</a>	version V2.1	05/10/2020	09/11/2020	No	No
<a href="#">Preprint results</a>		17/02/2022	18/02/2022	No	No
<a href="#">Basic results</a>		24/02/2022	24/02/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No