

# A pilot study of the ability of povidone-iodine (PVP-I) 0.5% aqueous solution oral/nasal spray and mouthwash to kill the SARS-CoV-2 virus in people with COVID-19

<b>Submission date</b> 21/05/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/10/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## 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 March 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.

Fluids (saliva and mucus) in the mouth, throat, and lungs of COVID-19 sufferers contain huge amounts of active SARS-CoV-2 virus; transmission of disease occurs when these fluids are coughed out or spread during normal breathing. Reducing the viral load in these areas may therefore reduce transmission of the disease.

The study tests the hypothesis that a common medical disinfectant, aqueous 0.5% povidone iodine (PVP-I) solution, administered to the mouth and nose of confirmed COVID-19 sufferers will reduce the quantity of the virus in the fluid lining those areas.

### Who can participate?

Adults  $\geq 18$  years old but  $\leq 75$  years old, recently hospitalised with COVID-19 disease.

### What does the study involve?

The trial will administer PVP-I to the mouth, nose and throat of proven COVID-19 patients who are not dependent on any ventilation. Viral levels from the mouth and nose will be determined immediately before and at several time points up to 2 hours after treatment in 2 different ways to quantify the reduction in virus from baseline over time in response to PVP-I use. Some patients will undergo the same process, but using water as a control.

### What are the possible benefits and risks of participating?

No benefits are expected to be received by a recipient of the PVP-I, as no curative intent is planned for the intervention, however, if proven, the PVP-I may stop patients from spreading the disease on to others. The risks to patients are very small. There is an exceptionally small risk of allergy (at least less than one in 1000) which might manifest as a burning sensation in the mouth or nose and swelling. There is a small theoretical risk of interference with the thyroid gland, although the dose received is very small, so that is why patients with thyroid disorders are excluded.

### Where is the study run from?

Royal Surrey County Hospital (UK)

### When is the study starting and how long is it expected to run for?

March 2020 to October 2020 (updated 06/08/2020, previously: July 2020)

### Who is funding the study?

1. British Association of Oral and Maxillofacial Surgeons
2. Royal Surrey County Hospital Charitable Fund
3. Surrey Perioperative, Anaesthesia & Critical Care Collaborative Research Group

### Who is the main contact?

Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn't ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

## Contact information

### Type(s)

Scientific

### Contact name

Dr Justin Kirk-Bayley

### ORCID ID

<https://orcid.org/0000-0001-9493-045X>

### Contact details

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

283182

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

IRAS 283182

## **Study information**

### **Scientific Title**

A pilot study of virucidal activity of povidone-iodine (PVP-I) 0.5% aqueous solution oral/nasal spray and mouthwash in people with COVID-19 and confirmed oral/nasal shedding of SARS-CoV-2

### **Acronym**

PICO

### **Study objectives**

SARS-CoV-2 is the virus causing the current COVID-19 pandemic; reducing transmission of the disease is critical globally. Fluids (saliva and mucus) in upper airways of COVID-19 sufferers contain huge amounts of active SARS-CoV-2; transmission of disease occurs when these fluids are coughed out or spread during normal breathing. Reducing the viral load in these areas may therefore reduce transmission of the disease.

The study tests the hypothesis that administration of a povidone iodine (PVP-I) nasal spray and mouthwash to COVID-19 sufferers reduces the SARS-CoV-2 viral titres found in their saliva and nose when compared to a water nasal spray and mouthwash.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 15/06/2020, NHS Health Research Authority (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 20/HRA/2711

## Study design

Single-arm non-randomised open-label uncontrolled interventional study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection)

## Interventions

The study will be conducted on 25 participants in a hospital setting. Each study participant will give a sample of saliva then use a spray or mouthwash/gargle of PVP-I for one minute followed by PVP-I atomised into each nostril using a simple device, not dissimilar to using a commercial nasal spray. Over the next 2 hours they will provide 5 further saliva samples for analysis.

5 of the 25 patients will undergo the same process, but using water as a control.

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Povidone iodine 0.5%

## Primary outcome(s)

Amounts of cultured SARS-CoV-2 and quantitative PCR results of viral RNA in saliva and nasal samples at baseline, and 5 further time points up to 2 h after administration. Results will be expressed as actual counts per ml saliva and the mean log reduction after application of PVP-I determined, taking into account any dilution effect by the mouthwash or spray which will be analysed in a control group given water instead of PVP-I

## Key secondary outcome(s)

Salivary viral loads after administration of PVP-I nasal spray or PVP-I mouthwash, at baseline, 5, and 20 min

## Completion date

28/02/2021

## Eligibility

### Key inclusion criteria

1. Adults aged  $\geq 18$  years and  $\leq 75$  years
2. Have confirmed COVID-19 symptoms and symptom onset within the past 10 days
3. Recently (within last 3-4 days) hospitalised with COVID-19 disease
4. COVID-19 disease proven by PCR testing for SARS-CoV-2 within the last 4 days

5. Capable of using a nasal spray device and the mouthwash required by the trial
6. Capacity and capability to give informed consent to take part in the trial

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Known sensitivity to PVP-I aqueous antiseptic solution or any of its listed excipients
2. Previously diagnosed thyroid disease
3. Chronic renal failure (stage  $\geq 3$  by eGFR MDRD)
4. Acute renal failure (KDIGO  $\geq$  stage 2: creatinine  $\geq 2x$  baseline)
5. Known pregnancy or currently breastfeeding
6. Current requirement for invasive or non-invasive ventilation or planned within next 6 hours
7. Patient undergoing or soon to undergo radioiodine treatment
8. Known dermatitis herpetiformis (Duhring's disease)
9. Current participation in research that is designed to, or is expected to alter the COVID-19 disease course or viral load.
10. Inability to communicate in English or read English

**Date of first enrolment**

04/11/2020

**Date of final enrolment**

31/12/2020

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Royal Surrey County Hospital  
Egerton Road

Guildford  
United Kingdom  
GU2 7XX

## Sponsor information

### Organisation

Royal Surrey County Hospital NHS Foundation Trust

### ROR

<https://ror.org/050bd8661>

## Funder(s)

### Funder type

Research council

### Funder Name

British Association of Oral and Maxillofacial Surgeons

### Funder Name

Royal Surrey County Hospital Charitable Fund

### Funder Name

Surrey Perioperative, Anaesthesia & Critical Care Collaborative Research Group

## Results and Publications

### Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

### IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			26/07/2023	No	No

[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes