ISRCTN13447477 https://doi.org/10.1186/ISRCTN13447477

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

Submission date
21/05/2020

Recruitment status
No longer recruiting

Registration date
22/05/2020

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary
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 ≥ 18 years old but ≤ 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.

Study website
http://www.spacer.org.uk/pico/

Contact information

Type(s)
Scientific

Contact name
Dr Justin Kirk-Bayley

ORCID ID
http://orcid.org/0000-0001-9493-045X

Contact details
Surrey Perioperative, Anaesthesia & Critical Care Collaborative Research Group
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX
01483 577 122 ext 4088
pico@spacer.org.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283182

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 hypothesis
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
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 measure
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

Secondary outcome measures

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

Overall study start date
15/03/2020

Overall study end date
28/02/2021

Eligibility

Participant inclusion criteria
1. Adults aged ≥18 years and ≤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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
22

Participant 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 ≥3 by eGFR MDRD)
4. Acute renal failure (KDIGO ≥stage 2: creatinine ≥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

Recruitment start date
04/11/2020

Recruitment end date
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital NHS Foundation Trust

Sponsor details
Egerton Road
Guildford
Surrey
Guildford
England
United Kingdom
GU2 7XX
+44 (0)1483 688 539
k.penhaligon@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.royalsurrey.nhs.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/11/2020

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?
HRA research summary			26/07/2023	No	No