

CONSENT FORM FOR PARTICIPANT

Project Title

A multicenter, single blind, randomized controlled trial of virucidal effect of Polyvinylpyrrolidone-Iodine on SARS-CoV-2 as well as safety of its application on nasopharynx & oropharynx of COVID-19 positive patients

BMRC Reg. No: 38624012021

Voluntary Consent Form for Participants
(Participant's age: 18 years or above)

Title of the Research Project: A multicenter, Single blind, randomized controlled trial of Polyvinylpyrrolidone-Iodine for its virucidal effect on SARS-CoV-2 as well as safety of application on nasopharynx & oropharynx of COVID-19 positive patient.

Principal Investigator:

Name: **Dr. Mostafa Kamal Arefin**

Indoor Medical Officer

Department of ENT & Head-Neck Surgery

Dhaka Medical College Hospital

Qualification: FCPS, MCPS, FICS (USA), DLSBS (Bangalore), BCS (Health), MBBS (DMC)

Detail Address: Department of ENT & Head-Neck Surgery, Dhaka Medical College Hospital

Mobile: +88016-71748866

Telephone (Off./Res):

e-mail: arefin61dmc@gmail.com

Study Site: Clinical trial will be carried out at Dhaka Medical College Hospital (DMCH), Kurmitola General Hospital (KGH), Kuwait-Moitree Hospital (KMH) and product development & quality assurance will be held at Bangladesh Reference Institute for Chemical Measurements (BRiCM)

Background

COVID-19 pandemic is the defining global health crisis of our time and the greatest challenge we have faced since World War Two. We have now reached the tragic milestone of two million deaths, and the human family is suffering under an almost intolerable burden of loss. The pandemic is much more than a health crisis; it's also an unprecedented socio-economic crisis. Stressing every one of the countries it touches; it has the potential to create devastating social, economic and political effects that will leave deep and longstanding scars. Every day, people are losing jobs and income, with no way of knowing when normality will return. Small island nations, heavily dependent on tourism, have empty hotels and deserted beaches. The International Labor Organization estimates that 400 million jobs could be lost

Povidone Iodine (Iodine with water soluble polymer Polyvinylpyrrolidone) or PVP-I is a proven and time trusted antiseptic agent having best possible (99.99%) virucidal effect in its only 0.23% concentration, against all viruses including SARS-CoV, MERS-CoV; even in SARS-COV-2 due to its nonspecific mode of action for virus killing and having no resistance [1,2]. Corona virus is transmitted by/via respiratory droplets or aerosol, produced from sneezing or coughing of infected persons to healthy individual through mouth and nose mainly [5, 6]. The routes of entry of coronavirus in human body are mouth, nose and eye. PVP-I products for throat and spraying the throat nose may have a preventive effect on COVID-19 and if it is proved in this study following human trial, this will be a landmark research in COVID-19 pandemic.

In line of this, PVP-I oro-nasal spray has been developed and proposed to use against corona virus disease. The proposed clinical trial would assess the safety and efficacy of this virucidal oro-nasal spray containing 0.6% povidone iodine. This oro-nasal spray is prepared following GMP

guideline, easily applied and has been found to be safe and effective. The clinical trial proposed here would be conducted in Bangladesh to specifically assess the safety and efficacy concern of this oro-nasal spray among Bangladeshi citizen. For preliminary assessment of efficacy and safety, a small scale randomized controlled trial with about 200 patient having COVID-19 positive within last 24 hours had already been taken place in Dhaka medical college hospital [Attachment 1] and the data has been collected from May 2020 to September 2020 which were very much satisfactory [Attachment 2].

Purpose

A multicenter, Single blind, randomized controlled trial of PVP-I is designed to be carried out among COVID-19 patients for evaluating its virucidal effects and to produce a safe oro-nasal spray of its tolerable concentration, intended to be used by healthy health personnel and individual attending COVID-19 patients as well as public gathering to prevent or reduce the transmission of SARS-CoV-2.

Types of Participation of the study respondents

Patient having report of RT-PCR test as positive within 24 hours for the 1st time will be included in the study.

Reason for asking for participation in the study

The study will be conducted among 768 COVID-19 patient (18 years and above) of Dhaka Medical College Hospital, Kurmitola General Hospital and Kuwait-Moitree Hospital. Besides more 20 Covid positive Patient (GP-B) mild multiple comorbidity and 10 healthy individual will be included (GP-C).

As you are apparently eligible, we request you to help us for the sake of huminity, in our efforts by allowing yourself in our study.

Procedures of the study and participants involvement

If you agree to participate in this study, the following procedures will be carried out:

A multicenter, Single blind, randomized controlled trial. This study is a randomized controlled trial (interventional study) as in following steps:

Group A (Number of subject -384X2 = 768)

Step 1: Enrollment of the study populations using inclusion and exclusion criteria

Step 2: Randomization to allocate experimental and controlled group

Step 3: Application of 0.6% PVP-I spray to experimental group and distilled water to control group

Step 4: Follow up (waiting for 2-5 minutes)

Step 5: Collection of nasopharyngeal and oropharyngeal sawab for RT-PCR test for both group

Step 6: Observation of the patients for 30 minutes for possible early adverse effects (if any) and subsequent management (if needed)

Step 7: Analysis

Group B (Number of subject 20)

Step 1: Selection of 20 patients with no or mild symptoms having multiple comorbidity and obtain their consent for the further tests

Step 2: Collection of 2nd, 3rd and 4th sample from nasopharynx and oropharynx (for RT-PCR test) hourly in a day after single application of PVP-I Oro-Nasal spray.

Group C (Number of subject 10)

Step 1: Selection of healthy volunteers who will use 2 puff of 0.6% PVP-I Oro-Nasal spray 3-4 times a day at least for one month

Step 2: Collection of blood & urine for determination of any change in biochemical marker (thyroid, kidney and liver functions)

During each visit the alth personnel will collect some information regarding your health status from you.

Potential benefits

You will be directly benefited by participation in this study as this medication will reduce the load of SARS-CoV-2 and transmissibility and possibly help your recovery faster from COVID-19 disease.

You will also get to know the screening test results and also physical examination result by a qualified doctor and scientist. By participating in this you will allow to evaluate a new virucidal chemical compound which is assumed to prevent COVID-19 diseases and save the world from this pandemic situation.

Risks, hazards and discomforts

You may feel some discomfort while spraying in nose and mouth. Otherwise no risk and hazard are associated in your participation in this study.

Reimbursements

In spite of the safety of the product, if you develops any problem that is likely to be due to the product, we will provide free treatment to you in this institute (DMCH or KGH or KMH), as appropriate within study time period. Moreover, if you develop any health problem, you will be able to communicate with us at any time for advice and treatment.

Confidentiality

Your personal and medical information including the laboratory test results will remain confidential and will be stored in a file cabinet under lock and key, under the responsibility of the principal investigator. After completing this study, your records will be locked, and none other than the investigators of this study and project staff directly dealing with you, study monitors, will be able to see them. However, disclosure of such information is also guided by the laws of Bangladesh. Your names and identity will not be used in analyzing results of the study, and/ or in sharing results with others, including publication in journals. By signing this consent, you are authorizing granting of such access only to these specific groups mentioned above. We will be happy to provide you the results of the tests when they become available.

Termination of study participation / Rights as a participant of a research study

By giving consent to participate in this study, you are committing to follow the protocol of the study. If you violate the protocol by doing the prohibited things or not co-operating with study personnel to perform their function, your participation will be terminated.

Even after giving consent to participate in this study, you can withdraw yourself from the study at any time without showing any reason. You and your family members will continue to receive the usual care and treatment of DMCH or KGH or KMH as before even though you do not participate in this study or you withdraw your consent after enrolment.

Providing answers to your questions

If you want to know more about the study you may ask us now and you will also be able to communicate later with the principal investigator of this study, either personally or by telephone at the address given below. If you want to know more about the rights of yourself as a participant of a research study, you would be able to contact Ethical committee of “BMRC”.

Name of Investigator: Dr. Mostafa Kamal Arefin
FCPS, MCPS, FICS (USA), DLSBS (Bangalore), BCS (Health), MBBS
(DMC), Indoor Medical Officer
Detail Address: Department of ENT & Head-Neck Surgery, Dhaka Medical College Hospital
Mobile: +88016-71748866 e-mail: arefin61dmc@gmail.com

Declaration by study participant:

The investigators/ study staff have explained the purpose, procedures, risks and benefits of participating in this study, the rights of research participants, and the confidential handling of the information and records to me and I have fully understood all. I understand that I may withdraw myself from the study at any time without showing any cause. I also understand that I have the right to get further information in future, and that my name and/or identity will not be used in the analyses of data and in sharing the results with others. Based on above, I am voluntarily giving my consent to enroll myself in this research study.

Participant's age: 18 years and above

Name of the participant: _____

Signature or left thumbprint of the participant: _____ Date _____

Name of witness: _____

Signature of witness: _____ Date _____

Thank you for your cooperation.

Name of the Interviewer (personnel securing consent): _____

Designation: _____

Signature of the study personnel securing consent: _____ Date: _____ Time: _____

Note: A signed and dated copy of this document will be given to you