Clinical Trial Details (PDF Generation Date :- Wed, 24 Feb 2021 17:31:37 GMT)

CTRI Number	CTRI/2020/06/025928 [Registered on: 16/06/2020] - **Trial Registered Prospectively**
Last Modified On	16/06/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Preventive Process of Care Changes
Study Design	Other
Public Title of Study	Local application of Povidone Iodine solution in nose and oral gargle for house hold contacts of COVID19 cases
Scientific Title of Study	Povidone Iodine Gargle and Intranasal application: A Quasi-Experimental study to reduce the spread of coronavirus infection in community with Covid-19 positive clusters.

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Sumita Shankar
Designation	Assoc.Prof
Affiliation	Rangaraya Medical College
Address	Rangaraya Medical College Department of Plastic Surgery Pithampuram, Road, Kakinada East Godavari ANDHRA PRADESH 533001 India
Phone	9848184495
Fax	
Email	sum713@yahoo.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Sumita Shankar
Designation	Assoc.Prof
Affiliation	Rangaraya Medical College
Address	Rangaraya Medical College Department of Plastic Surgery Pithampuram, Road, Kakinada East Godavari ANDHRA PRADESH 533001 India
Phone	9848184495
Fax	
Email	sum713@yahoo.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Vivekanand Kattimani
Designation	Professor
Affiliation	Sibar Institute of Dental Sciences
Address	Sibar Institute of Dental Sciences, Guntur Post- Takkellapdu Mandalam- Pedakakani Guntur ANDHRA PRADESH 522509

	India
Phone	9492473628
Fax	
Email	drvivekanandsk@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Dr Sumita Shankar, Department of Plastic Surgery Pithampuram, Road, Kakinada, Andhra Pradesh East Godavari ANDHRA PRADESH 533001 India

Primary Sponsor

Primary Sponsor Details	
Name	Dr Sumita Shankar
Address	Department of Plastic Surgery Pithampuram, Road, Kakinada, Andhra Pradesh East Godavari ANDHRA PRADESH 533001 India
Type of Sponsor	Other [Self sponsored]

Details of Secondary Sponsor

Name	Address
Dr Rakesh Kakkar	Department of Community & Family Medicine All India Institute of Medical Sciences Mangalagiri, Temporary campus at Government Siddhartha Medical College, Vijayawada, Andhra Pradesh-520008.

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Sumita Shankar	Covid Clusters of Guntur Dist	Guntur Urban Area Guntur ANDHRA PRADESH	9848184495 sum713@yahoo.com
Dr Limalemla Jamir	Covid Clusters of Krishna Dist	Vijayawada Urban area Krishna ANDHRA PRADESH	9914104152 lima.jamir@aiimsmangalagiri.edu.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IEC of All India Institute of Medical Sciences, Mangalagiri	Approved	30/05/2020	No
IEC of All India Institute of Medical Sciences, Mangalagiri	Approved	30/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Primary and Secondary contacts of COVID19 positive patients

Intervention / Comparator Agent

Type	Name	Details
Intervention	Povidone Iodine	2% Povidone Iodine gargle diluted to 1% (w/v) is used as oropharyngeal gargle. 15 ml of diluted 1% (w/v) Povidone Iodine 4 times daily gargle at prescribed time and intranasal application- 4 times daily using 1% (w/v) Povidone Iodine using applicator tip.

Comparator Agent	NIL	NIL

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	1- Household (HH) contacts of laboratory confirmed COVID-19 case(s) (more than or equal to one case per HH) 2- Willing to carry out the procedures four times daily for 7 days if provided with the gargle solution. 3- Resident in the area for the last six months. 4- Persons willing to be part of this protocol and sign informed consent.

Exclusion Criteria

Exclusion Criteria	
Details	1- Allergy (hypersensitivity) to povidone iodine. 2- Currently have or have ever had a thyroid problem, including swelling. 3- Pregnant women and lactating mothers. 4- Persons who are unable to carry out the intervention due to intellectual disability. 5- Persons who are too ill to participate.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
The Decrease in the attack rate of Primary and Secondary contacts of COVID19 patients and reduction of the Viral Load (Using cycle threshold values of RT PCR at different timelines)	7th day

Secondary Outcome

Outcome	Timepoints
Early recovery from infection and no relapse of infection.	7th and 21 st day

Target Sample Size	**Total Sample Size=**204 **Sample Size from India=**204 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	30/06/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**3 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	NIL
Brief Summary	

The COVID-19 pandemic caused by SARS-CoV-2 virus has spread to 215 countries with 3,525,116 confirmed cases and 243,540 deaths[1]. As per the latest update by Ministry of Health and Family Welfare (MoHFW), Government of India, COVID-19 cases continue to rise in the country with 31967 active cases and the state of Andhra Pradesh has 1717 confirmed cases and 36 deaths as of May 5, 2020. A major administrative and public health concern is spread of COVID-19 in slum communities as overcrowding, lack of basic amenities, poor nutrition and ill health pose high risk of transmission and casualties to COVID-19[2,3]. Moreover, most of the residents are low income groups who venture outside for daily wages or domestic work in peoples' homes thereby further increasing the chances of overall spread[4]. As COVID-19 [is] transmitted via droplets, fomites and even fecal contamination, context based strategies need to be implemented to prevent spread within and outside vulnerable slum populations[5,6]. However, preventive measures advocated by the World Health Organization and national nodal bodies, MoHFW and Indian Council of Medical Research such as frequent hand washing, physical/social distancing and home isolation maybe practically impossible in such communities[7,8]. Additionally, SARS-CoV-2 is more transmissible in households than the earlier SARS-CoV and Middle East Respiratory Syndrome coronavirus (MERS-CoV)[9]. Highest risk exposure group are household contacts of COVID-19 cases and attack rate is reported to be higher among household and non-household family contacts than that in health care or other settings[10]. Transmission by infected persons even before symptom onset, prolonged viral shedding and overburdened health facilities necessitates early protection of household contacts where COVID-19 cases are present[11,12]. In this context, Povidone Iodine (PVP-I), a widely used antiseptic in the healthcare setting with virucidal activity has the potential to contain the spread of COVID-19 from cases to household contacts. Rapid virucidal activity of Povidone Iodine (PVP-I) has been reported against Ebola virus (EBOV), the European reference virus (Modified vaccinia virus Ankara; MVA), MERS-CoV, influenza virus A (H1N1) and SARS coronavirus (SARS-CoV)[13-15]. In-vitro studies indicated that PVP-I products for gargling and spraying the throat inactivated the MERS-CoV, H1N1 virus and SARS-CoV in about 15 seconds to 2 minutes indicating the prophylactic role during outbreaks[16]. The recommended diagnostic testing for COVID-19 requires collection of nasopharyngeal and oropharyngeal swab specimens and higher viral load has been found in patient samples obtained from the nasopharynx than that those from the oropharynx[17,18]. Hence considering the routes of transmission which pose highest risk to close contacts, particularly among household contacts where other preventive measures mentioned earlier are difficult and healthcare staff who collect specimens for COVID-19 testing, PVP-I could serve as a protective barrier against SARS-CoV-2 virus. PVP-I is readily available in the market and intranasal application, oral gargles can be done easily by households and healthcare workers without any demanding procedures. Hence, the present study is aimed to assess the effectiveness of PVP-I in reduction of COVID-19 transmission from cases to household contacts. The study has significant policy level implications for community protection against COVID-19.

References

1. World Health Organization. Coronavirus disease (COVID-19) Situation Report-106. May 5, 2020. Available from: https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200505 covid-19-sitrep-106.pdf?sfvrsn=47090f63_2 [Last accessed on 2020 May 5].

2. Ahmed F, Ahmed NE, Pissarides C, Stiglitz J. Why inequality could spread COVID-19. The Lancet Public Health 2020. doi: 10.1016/S2468-2667(20)30085-2 [Epub ahead of print].

3. Krishnaiah K."Tirupati City With Many Slums ; An Ill Health Environment To The Piligirim Centre" in Martin J. Bunch, V. Madha Suresh and T. Vasantha Kumaran, eds., Proceedings of the Third International Conference on Environment and Health, Chennai, India, 15-17 December, 2003. Chennai: Department of Geography, University of Madras and Faculty of Environmental Studies, York University. Pages 226 – 232.

4. Corburn J, Vlahov D, Mberu B, Riley L, Caiaffa WT, Rashid SF, et al. Slum Health: Arresting COVID-19 and Improving Well-Being in Urban Informal Settlements. J Urban Health 2020. doi: 10.1007/s11524-020-00438-6 [Epub ahead of print].

5. World Health Organization. Coronavirus disease (COVID-19) advice for the public; 2019. Available from: https://www.who.int/ emergencies/diseases/novel-coronavirus-2019/ advice-for-public [Last accessed on 2020 May 4].

6. GoI, MoH&FW, DGHS (EMR. Revised Guidelines on Clinical Management of COVID – 19[Internet]. 2020 [cited 2020 May 4]. Available from: https://www.mohfw.gov.in/ pdf/RevisedNationalClinicalManagementGuidelineforCOVID1931032020.pdf

7. Xu Y, Li X, Zhu B, Liang H, Fang C, Gong Y et al. Characteristics of pediatric SARS-CoV-2 infection and potential evidence for persistent fecal viral shedding. Nat Med 2020;26(4):502-505.

8. van Doremalen N, Bushmaker T, Morris DH, Holbrook MG, Gamble A, Williamson BN, et al. Aerosol and

surface stability of SARS-CoV-2 as compared with SARS-CoV-1. N Engl J Med 2020;382(16):1564-7.

9. Jing QL, Liu MJ, Yuan J, Zhang ZB, Zhang AR, Dean NE, et al. Household Secondary Attack Rate of COVID-19 and Associated Determinants. medRxiv 2020. doi.https://doi.org/ 10.1101/2020.04.11 .20056010d.

10. Cheng HY, Jian SW, Liu DP, Ng TC, Huang WT, Lin HH. Contact Tracing Assessment of COVID-19 Transmission Dynamics in Taiwan and Risk at Different Exposure Periods Before and After Symptom Onset. JAMA Intern Med. 2020. doi: 10.1001/jamainternmed.2020.2020. [Epub ahead of print].

11. Liu J, Liao X, Qian S, Yuan J, Wang F, Liu Y, et al. Community transmission of severe acute respiratory syndrome coronavirus 2, Shenzhen, China, 2020. Emerg Infect Dis 2020;26(6). doi: 10.3201/eid2606.200239. [Epub ahead of print].

12. Wu Z, McGoogan JM. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China: summary of a report of 72 314 cases from the Chinese Center for Disease Control and Prevention. *JAMA*. 2020;323 (13). doi:10.1001/jama.2020.2648 [Epub ahead of print].

13. Kariwa H, Fujii N, Takashima I. Inactivation of SARS coronavirus by means of povidone-iodine, physical conditions and chemical reagents. Dermatology. 2006;212(Suppl. 1):119-23.

14. Eggers M. Infectious Disease Management and Control with Povidone Iodine. Infectious diseases and therapy. 2019;1:1-3.

15. Eggers M, Eickmann M, Zorn J. Rapid and effective virucidal activity of povidone-iodine products against Middle East respiratory syndrome coronavirus (MERS-CoV) and modified vaccinia virus ankara (MVA). Infect Dis Ther. 2015;4(4):491-501.

16. Eggers M, Koburger-Janssen T, Eickmann M, Zorn J. In Vitro Bactericidal and Virucidal Efficacy of Povidone-Iodine Gargle/Mouthwash Against Respiratory and Oral Tract Pathogens. Infect Dis Ther. 2018;7(2):249–59.

17. Zou L, Ruan F, Huang M, Liang L, Huang H, Hong Z, Yu J, Kang M, Song Y, Xia J, Guo Q. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. NEJM. 2020;382(12):1177-9.

18. To KK, Tsang OT, Yip CC, Chan KH, Wu TC, Chan JM, et al. Consistent Detection of 2019 Novel Coronavirus in Saliva. Clinical Infectious Diseases. Oxford Academic. Clin Infect Dis 2019. Available from:https://academic.oup.com/cid/advancearticle/ doi/10.1093/ cid/ciaa149/5734265 [Last accessed on 2020 April 3, 2020].