



# In vivo evaluation of the virucidal efficacy of Chlorhexidine and Povidone-iodine mouthwashes against salivary SARS-CoV-2

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## Main Information

**Primary registry identifying number**

LBCTR2021034768

**Protocol number**

CUER132020

**MOH registration number**

N/A

**Study registered at the country of origin**

No

**Study registered at the country of origin: Specify**

Lebanon

**Type of registration**

Retrospective

**Type of registration: Justify**

Research team was not aware of existence of LBCTR.

**Date of registration in national regulatory agency**

29/04/2020

**Primary sponsor**

Lebanese University

**Primary sponsor: Country of origin**

Lebanon

**Date of registration in primary registry**

07/03/2021

**Date of registration in national regulatory agency**

29/04/2020

**Public title**

In vivo evaluation of the virucidal efficacy of Chlorhexidine and Povidone-iodine mouthwashes against salivary SARS-CoV-2

**Acronym**

N/A

**Scientific title**

In vivo evaluation of the virucidal efficacy of Chlorhexidine and Povidone-iodine mouthwashes against salivary SARS-CoV-2

**Acronym**

N/A

**Brief summary of the study: English**

Antimicrobial mouthrinses are used in many clinical preprocedural situations for decreasing the risk of cross-contamination in the dental setting. The oral cavity is potentially high-risk transmitter of COVID-19. It is important to investigate the efficacy of mouthwash solutions against salivary SARS-CoV-2 in order to reduce the exposure of the dental team during dental procedures. This in vivo study is to evaluate the efficacy of 2 preprocedural mouthrinses in the reduction of salivary SARS-CoV-2 viral load. Saliva samples are collected from COVID-19 positive tested patients before and 5 minutes after mouthwash with 1% Povidone-iodine and 0.2% Chlorhexidine. SARS-CoV-2 rRT-PCR is then performed for each sample. Evaluation of the efficacy is based on difference in cycle threshold (Ct) value.

**Brief summary of the study: Arabic**

تستخدم محلولات مضادات الميكروبات كتطهير للفم قبل العلاجات السريرية في طب الأسنان. يعتبر تجويف الفم مصدر عدوى عالي الخطورة للعابى SARS-CoV-2 لذا هناك حاجة ماسة لإجراء تحقيق قائم على الأدلة للتأكد من فعالية محلول لغسول الفم ضد COVID-19. لجانحة Povidone-iodine 1% لتقليل التعرض أثناء إجراء العلاجات في عيادات طب الأسنان. تهدف هذه الدراسة إلى تقييم فعالية غسولي فم في الجسم الحي: قبل وبعد COVID-19 اللعابي. يتم جمع عينات اللعاب من مصابين بجانحة SARS-CoV-2 ضد فيروس Chlorhexidine 0.2% و Povidone-iodine 1%. يتم تقييم الفعالية على الفرق في قيمة عتبة الدورة SARS-CoV-2 rRT-PCR دقائق من غسول الفم. ثم يتم إجراء 5 (Ct) لكل عينة. يعتمد تقييم الفعالية على الفرق في قيمة عتبة الدورة SARS-CoV-2 rRT-PCR دقائق من غسول الفم. ثم يتم إجراء 5 (Ct) لكل عينة.

**Health conditions/problem studied: Specify**

COVID-19/Transmission during dental treatments.



**Interventions: Specify**

Mouthrinse.

Participants are invited:

- 1- To spit saliva in a container.
- 2- To mouthrinse with an antiseptic oral solution.
- 3- To collect a second post-wash solution.

**Key inclusion and exclusion criteria: Inclusion criteria**

COVID-19 Positive Tested Patients in Rafik Hariri University Hospital, Beirut, Lebanon, presenting mild or moderate symptoms and who (or guardians) give written informed consent.

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender****Key inclusion and exclusion criteria: Age minimum**

12

**Key inclusion and exclusion criteria: Age maximum**

100

**Key inclusion and exclusion criteria: Exclusion criteria**

- 1- COVID-19 Positive Tested Patients presenting severe cases.
- 2- COVID-19 Positive Tested Patients presenting disabilities (Mental retardation-Physical invalidity-Psychological troubles- Cognitive troubles affecting the capacity of discernation).
- 3- Patients (or guardians) who decline written informed consent.

**Type of study**

Interventional

**Type of intervention**

Preventive measures

**Type of intervention: Specify type**

N/A

**Trial scope**

Prophylaxis

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Blinded (masking used)

**Study design: Control**

Placebo

**Study phase**

N/A

**Study design: Purpose**

Prevention

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization****IMP has market authorization: Specify****Name of IMP****Year of authorization****Month of authorization****Type of IMP****Pharmaceutical class**

Antimicrobial

**Therapeutic indication**

Oral cavity disinfection

**Therapeutic benefit**

Reduce oral cavity microbial load and risk of infection transmission

**Study model**

N/A

**Study model: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration****Target follow-up duration: Unit****Number of groups/cohorts****Biospecimen retention**

Samples without DNA

**Biospecimen description**

Saliva sample before and after mouthwash for each participant

**Target sample size**

90

**Actual enrollment target size**

77

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

04/06/2020

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

31/12/2020

**Recruitment status**

Complete

**Recruitment status: Specify****Date of completion**

30/09/2020

**IPD sharing statement plan**

No

**IPD sharing statement description**

This is to be done upon request to respect the confidentiality of patients

**Additional data URL**



N/A

**Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
N/A	N/A

## Sources of Monetary or Material Support

Name
Lebanese University

## Secondary Sponsors

Name
N/A

## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Rola EL-ZEIN	Beirut	Lebanon	009613252480	roulaelzein@ul.edu.lb	Lebanese University
Scientific	Fouad AYOUB	Beirut	Lebanon	009613215290	fouad.ayoub@ul.edu.lb	Lebanese University

## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Lebanese University	Fouad AYOUB	Dentistry	Approved



## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Other Lebanon	01/05/2020	Fadi ABOU MRAD	cuemb@ul.edu.lb	009615463539

## Countries of Recruitment

Name
Lebanon

## Health Conditions or Problems Studied

Condition	Code	Keyword
COVID-19	Mouth, unspecified (C06.9)	Antiseptic oral mouthrinse;Prevention

## Interventions

Intervention	Description	Keyword
Mouthrinse	Saliva samples collected before and after mouthrinsing for each participant.	Oral antiseptic mouthwash; Salivary SARS-CoV-2 rRT-PCR

## Primary Outcomes

Name	Time Points	Measure
Change in cycle threshold (Ct) values of salivary SARS-CoV-2 (delta Ct) after mouthrinsing.	End of study	Delta Ct

## Key Secondary Outcomes

Name	Time Points	Measure
N/A	N/A	N/A



## Trial Results

**Summary results**

**Study results globally**

**Date of posting of results summaries**

**Date of first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**