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

**04/04/2025 23:32:09**

## 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**
06/03/2021

**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 الاسنان. يعتبر تجويف الفم مصدر عدوى عالي الخطورة لجائحة COVID-19. لذا هناك حاجة ماسة لإجراء تحقيق قائم على الأدلة للتأكد من فعالية محلول لغسول الفم ضد SARS-CoV-2 اللعابي. تهدف هذه الدراسة إلى تقييم فعالية غسولي فم في الجسم الحي: لتقليل التعرض أثناء إجراءالعلاجات في عيادات طب الأسنان. 1٪ Povidone-iodine و0.2٪ Chlorhexidine ضد فيروسSARS-CoV-2 اللعابي. يتم جمع عينات اللعاب من مصابين بجائحة COVID-19 قبل وبعد 5 دقائق من غسول الفم. ثم يتم إجراء SARS-CoV-2 rRT-PCR لكل عينة. يعتمد تقييم الفعالية على الفرق في قيمة عتبة الدورة (Ct).

**Health conditions/problem studied: Specify**
COVID-19/Transmission during dental treatments.

**Interventions: Specify**

Mouthrinse. Participants are invited to:
1- spit saliva.
2-mouthrinse with an antiseptic oral solution.
3- collect a second post-wash solution.

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

1- COVID-19 Positive Tested Patients in Rafic Hariri University Hospital presenting mild or moderate cases.
2- From all nationalities.
3- Participants (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- Participants (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 disinfection.

**Therapeutic benefit**

Reduce oral 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 confidentially 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 | Rola El-ZEIN | Beirut | Lebanon | 009613252480 | roulaelzein@ul.edu.lb | Lebanese University |

## Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|---|---|---|---|
| Rafic Hariri University Hospita | 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 | 2-Propanol (T51.2) | Antiseptic oralmouthrinse |

## Interventions

| Intervention | Description | Keyword |
|---|---|---|
| Mouthrinse | Saliva samples collected before and after mouthrinsing for each participant. | COVID-19;Dentistry;Oral antiseptic mouthwash;SARS-CoV-2 |

## Primary Outcomes

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