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

18/07/2025 04:02:39

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 فيرو SARS-CoV-2 قبل وبعد COVID-19 اللعابي. يتم جمع عينات اللعاب من مصابين بجائحة
5 دقائق من غسول الفم. ثم يتم إجراء SARS-CoV-2 rRT-PCR في قيمة عتبة الدورة (Ct) لكل عينة. يعتمد تقييم الفعالية على الفرق

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