



Evaluation of the efficacy of oral swabs and oropharyngeal saliva as diagnostic tools for COVID-19

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Main Information

Primary registry identifying number

LBCTR2021044780

Protocol number

CUER342021

MOH registration number

Study registered at the country of origin

No

Study registered at the country of origin: Specify

Lebanon

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

19/03/2021

Primary sponsor

Lebanese University

Primary sponsor: Country of origin

Lebanon

Date of registration in primary registry

18/04/2021

Date of registration in national regulatory agency

19/03/2021

Public title

Evaluation of the efficacy of oral swabs and oropharyngeal saliva as diagnostic tools for COVID-19

Acronym

Scientific title

Evaluation of the efficacy of oral swabs and oropharyngeal saliva as diagnostic tools for COVID-19

Acronym

Brief summary of the study: English

Nasopharyngeal and oropharyngeal swab sampling for COVID-19 diagnosis is technically challenging, requires healthcare professionals, causes discomfort and may impose risk for aerosol generation. These drawbacks necessitate the implementation of additional diagnostic approach. Saliva-based test allows self-collection and can spare healthcare professionals to be at risk during collecting nasopharyngeal or oropharyngeal samples, thereby preserving personal protective equipment for use in patient care rather than sampling and testing. Consequently, broader testing than the current methods of nasal or throat swabs will significantly increase the number of people screening, leading to more effective control of the spread of COVID-19. This study aims to detect the efficacy of oral (lingual and sublingual) swabs and oropharyngeal spit saliva as a diagnostic tool for the COVID-19.

Brief summary of the study: Arabic

تحديًا تقنيًا، كما يتطلب متخصصين في الرعاية الصحية، ويسبب COVID-19 بشكل أخذ عينات مسحة من البلعوم-الأنف والبلعوم-الفم لتشخيص عدم الراحة للمريض وقد يشكل خطرًا في توليد الرذاذ اللعابي. هذه العوائق تتطلب تنفيذ نهج تشخيصي آخر. إن الاختبار القائم على اللعاب يسمح بالتجميع الذاتي من قبل المريض ويمكن أن يجنب متخصصي الرعاية الصحية التعرض للخطر أثناء COVID-19 لتشخيص الإصابة بالجمع عينات مسحة البلعوم-الأنف والبلعوم-الفم، كما يوفر البسة الحماية الشخصية لاستخدامها في رعاية المرضى بدلاً من ارتداؤها خلال أخذ العينات والاختبار. اعتمادًا على اللعاب المجمع من أماكن مختلفة في الفم: سطح COVID-19 تهدف هذه الدراسة إلى تحديد مدى فعالية تشخيص الإصابة باللسان، تحت اللسان، و اللعاب المجمع من البلعوم.



Health conditions/problem studied: Specify

COVID-19/ Practical and safe diagnostic tools

Interventions: Specify

From each enrolled participant are collected: 1 nasopharyngeal swab, 1 lingual swab, 1 sublingual swab and 1 oropharyngeal spitted saliva.

Key inclusion and exclusion criteria: Inclusion criteria

1. COVID-19 Positive Tested Patients from all nationalities, presenting mild or moderate cases (not intubated and not under oxygen).
2. Patients whom (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

80

Key inclusion and exclusion criteria: Exclusion criteria

1. COVID-19 Positive tested patients presenting disabilities (Mental retardation-Physical invalidity-Psychological, troubles- Cognitive troubles affecting the capacity of discernation).
2. Patients presenting hyposalivation.
3. Patients whom (or guardians) decline written informed consent.

Type of study

Interventional

Type of intervention

Diagnostic

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

N/A

Study design: Masking

N/A

Study design: Control

N/A

Study phase

N/A

Study design: Purpose

Diagnostic

Study design: Specify purpose

N/A

Study design: Assignment

Single

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

N/A

Therapeutic indication

Diagnostic tool for COVID-19

**Therapeutic benefit**

Salivary tool is considered easier to collect, less invasive for patients testing for COVID-19 and more safe regarding the SARS-CoV-2 cross contamination among health care professionals collecting samples for COVID-19 diagnosis

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**

None retained

Biospecimen description

Nasopharyngeal secretion
Saliva from the dorsal surface of the tongue
Saliva from the sublingual region
Oropharyngeal spitted saliva

Target sample size

90

Actual enrollment target size**Date of first enrollment: Type**

Anticipated

Date of first enrollment: Date

19/04/2021

Date of study closure: Type

Anticipated

Date of study closure: Date

31/12/2021

Recruitment status

Pending

Recruitment status: Specify**Date of completion**

18/06/2021

IPD sharing statement plan

No

IPD sharing statement description

IPD are not to be shared 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
Lebanese University	Hassan HAMAD	Public Health	Approved
Saint-Georges Hospital	Souha FAKHREDDINE	Infectious diseases	NA
Bahman Hospital	Olfat AWAD	Internal Medicine	NA

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Other Lebanese University	19/03/2021	Fadi ABOU MRAD	cuemb@ul.edu.lb	009615463539

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
COVID-19	Viral infection, unspecified (B34.9)	COVID-19;Diagnostic tool;Salivary swabs

Interventions

Intervention	Description	Keyword
Saliva sample collections + Nasopharyngeal swab	Nasopharyngeal swab + salivary swab from tongue dorsal surface+sublingual salivary swab+oropharyngeal spitted saliva are collected from each participant	COVID-19;salivary swabs;nasopharyngeal swabs

Primary Outcomes

Name	Time Points	Measure
To detect the efficacy of oral swabs and oropharyngeal spitted saliva as a diagnostic tool for the COVID-19.	End of study	Salivary SARS-CoV-2 Ct from salivary swabs



Key Secondary Outcomes

Name	Time Points	Measure
To compare Salivary SARS-CoV-2 (from lingual,sublingual and oropharyngeal spitted saliva) cycle threshold (Ct) to nasopharyngeal SARS-CoV-2 Ct	End of study	Nasophayngeal SARS-CoV-2 Ct

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