# 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 spitted 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 يشكل 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 اخر . ان الاختبار القائم على اللعاب يسمح بالتجميع الذاتي من قبل المريض ويمكن أن يجنب متخصصي الرعاية الصحية التعرض للخطر أثناء COVID-19 لتشخيص الإصابة بال جمع عينات مسحة البلعوم-الأنف والبلعوم-الفم، كما يوفر البسة الحماية الشخصية لاستخدامها في رعاية المرضى بدلاً من ارتدائها خلال أخذ العينات والاختبار.
اعتمادا على اللعاب المجمع من اماكن مختلفة في الفم: سطح COVID-19 تهدف هذه الدراسة الى تحديد مدى فعالية تشخيص الإصابة بال اللسان, 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 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 | 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**