TCTR ID : TCTR20230210007

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date :	10 February 2023
First Posted Date :	10 February 2023
Last Update Posted Date :	10 February 2023

Title

Public Title :	Prognostic factors Associated with Early Recovery of Olfactory Dysfunction in COVID-19 patients
Acronym :	No Data
Scientific Title :	Prognostic factors Associated with Early Recovery of Olfactory Dysfunction in COVID-19 patients
Sponsor ID/ IRB ID/ EC ID :	3061
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20230210007
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	COA.MURA2021/593
Date of Approval :	21 July 2021
Board Name :	Human Research Ethics Committee
Board Affiliation :	Faculty of Medicine Ramathibodi Hospital, Mahidol University
Board Contact :	Business Phone : 6602012175 Ext. No Data
	Business Email : raec.mahidol@gmail.com
	Business Address : 270 Rama 6 Rd. Phayatai Ratchathewi Bangkok 10400

Sponsor

Source(s) of Monetary or Material Supports :	Faculty of Medicine, Ramathibodi Hospital, Mahidol University
Study Primary Sponsor :	Faculty of Medicine, Ramathibodi Hospital, Mahidol University
Responsible Party :	Name/Official Title : Faculty of Medicine, Ramathibodi Hospital, Mahidol University
	Organization : Faculty of Medicine, Ramathibodi Hospital, Mahidol University
	Phone : 022011701 Ext. No Data
	Email : raec.mahidol@gmail.com
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	To find the prevalence of early olfactory dysfunction and factors associated with early olfactory recovery, the Median time to recovery of olfactory dysfunction in COVID-19 patients

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	COVID-19 patients with olfactory dysfunction
Keywords :	COVID-19, Delta strain, loss of smell, olfactory dysfunction, hyposmia, early recovery, prognostic factor

Eligibility

Inclusion Criteria :	1. Age > 18years 2. Confirmed COVID-19 test identified through nasal swabs and positive reverse transcriptase polymerase chain reaction (RT-PCR) with new onset of smell dysfunction
Gender :	Both
Age Limit :	Minimum : 18 Years Maximum : N/A (No limit)
Exclusion Criteria :	1. History of smell loss before COVID-19 era. 2. Previous history of rhinological diseases such as chronic rhinosinustis, nasal tumor, anatomical abnormalities of the nose. 3. Previous neurosurgical,

otorhinolaryngological or maxillofacial surgery that cause alteration in sinonasal apparatus. 4. Pregnancy 5. Dementia, or other conditions associated with an inability to complete the evaluations. 6. The patients who refuse to enroll the study.

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates
- Study Start Date (First enrollment) : 01 August 2021 — Indicate Type : Actual
- Completion Date (Last subject, Last visit) : 10 November 2021 — Indicate Type : Actual
- Study Completion Date : 08 December 2021 — Indicate Type : Actual

Design

Study Type : Observational

Primary Purpose : Other

Number of Groups : 1

Study Endpoint Classification : N/A

Sample size
- Planned sample size : 290
- Actual sample size at study completion : 339

Observation Group 1
- Group name : COVID-19 patients with olfactory dysfunction
- Group Description : COVID-19 patients who confirm with RT-PCR with new onset of smell dysfunction which confirm with the smell test kit

Outcome

Primary Outcome

1. Outcome Name : prevalence of early olfactory recovery

Metric / Method of measurement : the complete improvement of ten in the VAS score of smell sensation on each specific odor in the first two weeks of follow-up

Time point : 2 weeks after first evaluation

Secondary Outcome

1. Outcome Name : 1. factors associated with early olfactory recovery 2. median time to complete recovery of smell loss

Metric / Method of measurement : 1. Odd ratio was used to find associated factors and early olfactory recovery 2.median time is the time participants reached the total smell score of four specific odors

Time point : 6 weeks after first evaluation

Location

Section A : Central Contact

Central Contact	First Name : Pattraporn	Middle Name :	Last Name : Kreesaeng
	Degree : M.D.	Phone : 0961492651 Ext. : No Data	Email : pattrapornkreesag.fern@gmail.com
Central Contact Backup	First Name : Kangsadarn	Middle Name :	Lastname : Tanjararak
	Degree : M.D.	Phone : 0839166638 Ext. : No Data	Email : kang006611@gmail.com

Section B Facility Information and Contact

1. Site Name : Ramathibodi hospital

	City : Ratchathewi	State/Province : Bangkok	Postal Code : 10400
	Country : Thailand	Recruitment Status : Completed	
Facility Contact	First Name : Pattraporn	Middle Name :	Last Name : Kreesaeng
	Degree : M.D.	Phone : 0961492651 Ext. : No Data	Email : pattrapornkreesag.fern@gmail.com
Facility Contact Backup	First Name : Kangsadarn	Middle Name :	Last Name : Tanjararak
	Degree : M.D.	Phone : 0839166638 Ext. : No Data	Email : kang006611@gmail.com

Investigator Name	First Name : Pattraporn	Middle Name :	Last Name : Kreesaeng
	Degree : M.D.	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Pattraporn	Middle Name :	Last Name : Kreesaeng
Degree : M.D.	Phone : 0961492651 Ext. : No Data	Email : pattrapornkreesag.fern@gmail.com
Postal Address : 270 Rama 6 Rd. Phayathai Ratchathewi		
State/Province : Bangkok	Postal Code : 10400	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine, Ramathibodi Hospital, Mahidol University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Pattraporn	Middle Name :	Last Name : Kreesaeng
Degree : M.D.	Phone : 0961492651 Ext. : No Data	Email : pattrapornkreesag.fern@gmail.com
Postal Address : 270 Rama 6 Rd. Phayathai Ratchathewi		
State/Province : Bangkok	Postal Code : 10400	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine, Ramathibodi Hospital, Mahidol University		

Summary Results

Date of posting of results summaries :	01 July 2022
Date of first journal publication of results :	Not yet published
Baseline Characteristics :	Three hundred forty-eight participants enrolled in the study, 8 patients lost to follow-up, and 1 patient died from COVID-19 respiratory failure; thus, 339 completed the outcome measurements through the follow-up periods. Of 339, there were 120 males (35.4%), the mean age was 39.9+13.5 years, and the average BMI was 24.2+4.5. Most participants did not have a history of previous or current smoking (75.2%). During the period of the study, 92 participants (27.1%) received a complete vaccination (2 shots), 145 (42.8%) received partial vaccination (1 shot), and 102 (30.1%) had no vaccination. There were 42 participants (12.4%) who had allergic rhinitis, 9 (2.7%) had lower respiratory diseases, 37 (10.9%) had hypertension, and 16 (4.7%) had diabetes. Only 8 participants (2.4%) had used intranasal or inhaled corticosteroids. The median duration of olfactory dysfunction was 0 days (IQR: 0.0, 2.0). Some participants reported concomitant symptoms other than olfactory dysfunction, including 245 (72.3%) had a fever, 302 (89.1%) had URI symptoms, 181 (53.4%) had fatigue symptoms, and 136 (40.1%) had taste alteration. One hundred forty participants (41.3%) received anti-viral drugs, and 43 (12.7%) received systemic corticosteroids as a part of COVID-19 treatment. Thirty-four participants developed COVID-19 pneumonia, and 12 (3.5%) needed oxygen therapy.
Participant Flow :	The seven disposable smell test kits were delivered to 348 participants who met the eligible criteria. Each smell test kit had four specific odors, including orange, coffee, jasmine, and fish sauce, in a 5-mL amber glass bottle sealed with plastic wrap to maintain odorant. The odors used in the study were culturally recognized, and the concentrations were identical to a previous study investigating odor identification in the local normosmia population. All participants received a quick response code to scan the instructional video for odor testing. The visual analog scale of smell sensation of the four specific odors was collected via the telephone at baseline and every week until six weeks follow-up. loss follow-up 8 participants died from COVID-19 pneumonia 1 participants total analysis participants are 339
Adverse events :	no
Outcome Measures :	- the primary outcome was the prevalence of early olfactory recovery. The early recovery of smell loss was defined as the complete improvement of ten in the VAS score of smell sensation on each specific odor in the first two weeks of follow-up. The authors determined the cut of two weeks as an early recovery of olfactory dysfunction. - secondary outcomes were the analysis of factors associated with the early olfactory recovery and the median time to complete recovery of smell loss evaluated by the time participants reached the total smell score of four specific odors
Brief Summary of Results :	The median time to olfactory recovery is two weeks, and patients with no allergic rhinitis, concomitant URI symptoms, taste alteration, developed pneumonia, and higher BMI have a better prognosis for improving smell loss in the earlier period.

Deidentified Individual Participant-level Data Sharing

Plan to share IPD :	Yes
Plan description :	sharing 1 year after publication for a period of 2 years

Publication from this study

MEDLINE Identifier :	No Data

URL link to full text publication : No Data