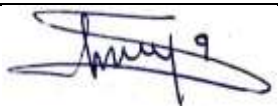




The Arab Republic of Egypt
Ministry of Higher Education
Health Research Ethics Committee
Assiut University
Faculty of Medicine

NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROPOSAL
--

Applicant

<input type="checkbox"/> Name: Sherifa Ahmed Hamed
<input type="checkbox"/> Institute: Assiut University, Faculty of Medicine
<input type="checkbox"/> Current position: Professor of Neurology
<input type="checkbox"/> Address / e-mail: Department of Neurology and Psychiatry, Floor # 7, Room # 4, Hospital of Neurology and Psychiatry, Assiut University Hospital Assiut, Egypt P.O.Box 71516 Telephone: +2 088 2085106 Cell phone: +2 01115324560 Fax : +2 088 2333327 +2 088 2332278 email: hamed_sherifa@yahoo.com ; hamedsherifa@aun.edu.eg
<input type="checkbox"/> Signature 

Title of the study

Evaluation of children and adults with post-covid-19 persistent smell, taste and trigeminal chemosensory disorders: A Hospital based study

Introduction/methodology/data collection/data analysis

Smell loss is the most frequent acute manifestation of covid-19 infection with an estimated prevalence of 40-86% in adults and 16-20% in children. Smell disorders (loss or distortion) are also the most frequent long-lasting complications of covid-19 infection with an estimated prevalence of 20-40% in adults. Compared to smell, taste disorders are less frequent acute manifestation of viral infection (occurring in 10-42% of adults) and long-lasting complications of covid-19 infection. Reports about the prevalence and prognosis of these disorders in children are few or even lacking compared to adults. Also the mechanisms and treatment of these persistent disorders are still challenges. Evidence from experimental studies suggested that injury and degeneration of the neuronal olfactory and gustatory sensory epithelia by severe peripheral viral infection and its immunopathology and the delay or lack of neuronal regeneration might contribute to these disorders. This work aimed to determine the patterns of post-covid-19 smell and taste disorders at onset in a cohort of adults and children and quantify the extent of these disorders using validated objective measures. The intra- (within the same group) and inter- (adults versus children) individual variability in demographics, clinical characteristics and quality of life variables, will be determined. The inter-individual variability of clinical characteristics within same family members infected with covid-19 infection will also be determined.

This study will include about 200 patients (adults = ~100; children = ~ 100). Recruitment of patients will be done from the outpatient clinic of the Otolaryngology department of Assiut University Hospital, Assiut, Egypt. Assessment will include Otolaryngology and neuropsychiatric evaluations (histories and examination and imaging). Measurements will include a clinical questionnaire (for smell and taste); sniffin' odor, taste and flavor identification tests and the Questionnaire of Olfactory Disorders-Negative Statements (sQOD-NS) for determination of quality of life of patients in relations to smell and taste disorders.

Data will be analyzed using SPSS (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). Descriptive statistics will be demonstrated as numbers (%) and mean (SD). Comparative statistics (intra- and inter- individuals) between variables for adults and children will be performed using independent sample *t-test*, Chi square test and Mann-Whitney U test. Correlation analysis will be done between total scores of sQOD-NS and different demographic and clinical variables (age, gender, duration of disorders, presence or absence of parosmia, presence or absence of taste/flavor loss) using Spearman's correlation coefficient. The level of statistical significance will be set at $P < 0.05$ with a 95% confidence interval.

Budget

Personal

Confidentiality

As a corresponding author, I declare that written informed consent was obtained from the patients for

publication of their clinical, laboratory and socioeconomic and psychometric data.

For office use only

Proposal No.: AUH_SARS-CoV2_SAH/2019

Date Received: 20th July 2019

Approved

