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This is to certify that **Mr. Krutik Chetan Jain** student of **MBBS-I** of **Mahatma Gandhi Missions Medical College, Navi Mumbai** has completed the Short Term Studentship (STS) for a period of two months during 2022 under the guidance of **Dr. Rita Manoj Khadkikar** for the project entitled “**Assessing risk factors for Obstructive Sleep Apnea (OSA) in hypertensive patients**” (2022-05630) and the report was satisfactory.

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ये पासबुक 3 महीने के अंदर आपरेट होना  
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This Pass Book Before entry within 3 month



## **SHORT-TERM STUDENTSHIP (STS-2022)**

### **Proposal Result**

1. The final list of students selected for STS-2022 Program is displayed below in order of their STS-2022 Reference ID. **There will be no second list.**  
Please note: Always quote your STS Reference ID for any future correspondence emails to ICMR.  
**DO NOT SEND EMAILS ASKING FOR REASONS OF REJECTION/COMMENTS etc. Such emails will not be entertained or corresponded (pl. see the STS Guidelines for details).**
2. Each application was reviewed independently by group of Experts for its scientific value and selections have been made on the review done.
3. The 'Approved' students as listed below for STS-2022 may carry out the proposed research work and prepare the report in any two months from 18<sup>th</sup> May, 2022 to 31<sup>st</sup> October, 2022.
4. Research should be done after appropriate Institutional Ethics Committee (IEC) approval has been obtained. The ethical clearance letter has to be submitted along with report (**IEC approvals should be taken by latest by 31<sup>st</sup> August, 2022, any IEC letter/approvals taken after 31<sup>st</sup> August, 2022 will not be considered as the student will not get two months of time for carrying out the work and submit the due report by the deadline given.**)
5. ONLINE report submission will commence from 16<sup>th</sup> August, 2022 (Tuesday, 10:00AM onwards) to 31<sup>st</sup> October, 2022 (Monday, till 5:00PM) only.
6. The decisions taken by ICMR is/will be final for all. No correspondence in the matter will be entertained.

**IMPORTANT-** The \*Application Attestation Form (\*AAF) submitted by some of the selected students have some discrepancies which need to be rectified and hence their result has been declared as 'withheld'. Only the 'withheld' students will be sent a separate email shortly, to re-submit the correct AAF to ICMR, as applicable for each of them. The revised and corrected AAF should be sent by email to [stshrd2017@gmail.com](mailto:stshrd2017@gmail.com) by 10<sup>th</sup> June, 2022 (by 5:30pm). The final result for withheld students will be updated only after reviewing the revised AAF after 10<sup>th</sup> June, 2022.  
If required AAF is not received by 10<sup>th</sup> June, 2022 the selection of the 'withheld' students shall stand cancelled, without any further information.

Kindly read the detailed report submission guidelines and instruction given on the STS website

GENERAL ENQUIRIES to be sent through email to [stshrd2017@gmail.com](mailto:stshrd2017@gmail.com) or call on extn.no. 306, 369

691	2022-05532	Ms. Jagatishi Kaur	Approved
692	2022-05538	Mr. Rajveer Mann	Approved
693	2022-05564	Ms. Arya Pg	Approved
694	2022-05569	Ms. Madhura Kayara	Approved
695	2022-05581	Ms. Roopam	Approved
696	2022-05587	Ms. Anjali Raju	Approved
697	2022-05588	Mr. Unmesh Rajendra Sawant	Approved
698	2022-05597	Ms. Gavireddy Sravani	Approved
699	2022-05618	Ms. Ayushi Himanshu Patel	Withheld
700	2022-05621	Ms. Diyanka Paul	Approved
701	2022-05630	Mr. <b>Krutik Chetan Jain</b>	Approved
702	2022-05643	Mr. Jayaprakash V	Approved
703	2022-05667	Mr. Vikash Kumar Rai	Withheld
704	2022-05683	Ms. Ann Merin Mathews	Approved
705	2022-05689	Ms. Mounika Chintada	Approved
706	2022-05696	Mr. Hariharan Seshadri	Approved
707	2022-05705	Ms. Mahek Ajay Chauksey	Approved
708	2022-05706	Ms. Isha Goel	Approved
709	2022-05730	Mr. Niranjana Vijayan	Approved
710	2022-05742	Mr. Pugazhenthil C	Approved

**REFERENCE ID: - 2022-05630**

**TITLE: - Assessing risk factors for obstructive sleep apnea (OSA) in hypertensive patients**

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## **INTRODUCTION: -**

Chronic diseases like hypertension diabetes require lifestyle modifications for the management. It is seen that poor-quality sleep due to various sleep disorders can initiate or aggravate hypertension and metabolic disorders.

Sleep disturbances are common and are often undiagnosed among people Obstructive sleep apnoea (OSA) is a common disorder where individuals breathe normally during wakefulness but in sleep there is recurrent complete or partial upper airway obstruction, resulting in intermittent hypoxemia, oxygen desaturation, hypercapnia and sleep fragmentation. (1-4,6,8) OSA phenotypes are identified that vary in the pathogenesis which give a greater insight into its management (5). Individuals with OSA are usually obese, complain of excess daytime sleepiness, morning headaches, snoring and gasping at night (1).

OSA is a recognized cause of secondary hypertension as it causes overactivity of the sympathetic nervous system, alterations in the structure and function of vascular system due to intermittent hypoxia and hypercapnia (2,3). It is also a established risk factor for resistant hypertension (4).

Even mild OSA if untreated can lead to increased cardiovascular morbidity and mortality (3). Sleep disorders are seen in 40% to 80% of patients with hypertension, coronary artery disease (CAD), and heart failure.

It is important to note and examine the risk factors of OSA in hypertension for better management of hypertension and good patient outcome. OSA can then be confirmed by the gold standard polysomnography and managed using CPAP. (1)

In our study we will be assessing the risk factors of OSA in hypertensive patients using the STOP BANG questionnaire, and assessing the airway using Mallampati score. (9,10) We hypothesize that higher scores of the above parameters, higher the risk of OSA leading to poor control of hypertension.

**OBJECTIVES: -**

1. To assess risk of OSA using STOP-BANG questionnaire in hypertensive patients
2. To assess the airway patency using Mallampati score as a risk factor of OSA in Hypertensive patients.
3. To observe association of severity of Hypertension with STOP BANG score
4. To observe association of severity of Hypertension with Mallampati score
5. To observe association of STOP BANG score with Mallampati score

## **METHODOLOGY: -**

- **Study Design-**

1. This is an observational, cross sectional study carried out in the Physiology Department in collaboration with Medicine and Cardiology department of MGM hospital, Kamothe, Navi Mumbai after the approval by Institutional Ethics Committee.
2. Sample size: 100 patients.

- **Inclusion criteria of subjects-**

The study will be conducted on hypertensive patients, both male and female, in the age group of 30-60 years.

- **Exclusion criteria of subjects-**

Excluding the patients who have Co-morbidity like Diabetes, Renal diseases, Asthma, respiratory disorders, anxiety disorders.

- **Material-**

1. **STOP-BANG questionnaire-** It is a concise, easy-to-use screening tool use to assess the prevalence of OSA. It consists of 8 dichotomous (Yes/No) items related to the clinical features of sleep apnea. The total score ranges from 0 to 8. Patients can be classified for OSA risk based on their respective scores (4). It enquires about Snoring, tiredness, Gasping, Blood pressure, BMI, age, neck circumference and sex.

STOP-BANG scores-

- 0-2 :- Low risk of OSA
- 3-4 :- Moderate risk of OSA
- >5 :- High risk of OSA

2. Libra Weighing machine for checking the weight in Kilograms

3. Height will be recorded in centimeters

4. Measuring tape for measuring neck circumference

5. Torch for examining the oral cavity

- **Method-**

1. Approval by Institutional Ethics Committee will be obtained.
2. After diagnosis of hypertension by the physician in the Medicine department the participant will be referred for this study. Based on the Blood Pressure we can categorize the participants into as per Seventh Report of the Joint National Committee (JNC7)

Blood Pressure Classification	SBP mmHg	DBP mmHg
Normal	<120	<80
Prehypertension	120–139	or 80–89
Stage 1 Hypertension	140–159	or 90–99
Stage 2 Hypertension	>160	or >100



3. Written informed consent will be obtained from the participants (sample size 100) in their local languages.

4. Participant fills in

- a. Case study form
- b. STOP-BANG questionnaire (provided in local languages) is filled for which we need to measure and calculate
  - a. Height is measured in centimeters
  - b. Weight is measured in Kilograms
  - c. Body Mass Index (BMI) is calculated

**Body Mass Index (BMI = kg/m<sup>2</sup>)** is calculated by measuring the weight in Kilograms and height in centimeters.

Categories based on Asian BMI are

- Underweight : <18.5
- Normal : 18.5–22.9
- Overweight : 23–24.9
- Obese : ≥25

**Neck circumference** is measured perpendicular to the long axis of the neck at a point just below the larynx Adam's Apple and while the person is looking straight ahead during measurement, with shoulders down (not hunched). Round the neck measurement up to nearest ½ inch.

- In females > 16 inches
- In males > 17 inches is a risk factors associated with OSA

5. STOP-BANG Scores are calculated and based on their responses they are divided into 3 groups, low, moderate and High risk of OSA.

6. **Mallampati Score-** It is used mainly to predict ease of endotracheal intubation and it also helps to note the grade of OSA. The score is assessed by asking the patient, in a sitting posture, to open their mouth and to protrude the tongue as much as possible (5). With all the required precautions and physical distancing patient is asked to open the mouth and from a distance, oral cavity of patient is examined and based on Mallampati scores patients will be categorized into 4 groups

- Class 1: Visualization of the soft palate, fauces, uvula, both anterior and posterior pillars
- Class 2: Visualization of the soft palate, fauces, uvula
- Class 3: Visualization of the soft palate and base of the uvula
- Class 4: Soft palate is not visible at all.

7. Observation of association of severity of Hypertension with STOP BANG score

8. Observation of association of severity of Hypertension with Mallampati score

9. Observation of association of STOP BANG score with Mallampati score

• **Statistical tests for analysis:-**

1. Descriptive statistics in terms of percentage and frequency.
2. Chi square test.
3. Logistic Regression.
4. Wilcoxon Rank Sum Test/Mann Whitney Test

## **IMPLICATIONS: -**

Incidence of hypertension is increasing and it needs to be managed well to prevent its aggravation. Poor control of blood pressure can lead coronary artery disease (CAD) and heart failure.

OSA is a risk factor for hypertension. Even a mild case of OSA has shown to increase the cardiovascular morbidity and mortality. Screening the cases by the physician for OSA by assessing for risk factors and timely diagnosis by polysomnography (PSG) and treatment by CPAP is crucial to prevent many cardiometabolic disorders.

Awareness among the doctors and patients can help in proper treatment of hypertension with a positive patient outcome.

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## Participant Information Sheet

### Study Title:

**“Assessing risk factors for obstructive sleep apnea (OSA) in hypertensive patients”**

### Principle researcher:

### Research site:

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

#### **1. What is the purpose of the study?**

To observe the risk factors for OSA in diagnosed hypertensive patients using STOP BANG questionnaire and assessing the upper airway through an oral examination for Mallampati Score.

#### **2. Who will do the study?**

#### **3. Why have I been invited to participate in this study?**

You are eligible to participate as you fulfill the inclusion criteria for the following study

#### **4. What is the study procedure?**

After explaining and taking informed consent from the participant, STOP BANG questionnaire is filled. An oral examination for assessing the upper airway is done for Mallampati score. The associations of hypertension with STOP BANG score and Mallampati score are observed.

#### **5. What are the risks/discomforts of taking part in the study?**

Since this study is noninvasive there will be no risk involved or no discomfort will be experienced

#### **6. What are the possible benefits of taking part in this study?**

This study will help us in understanding whether there are risk factors for OSA. Those with risk factors will be explained about the potential harm caused by OSA and will be advised sleep study for better management of hypertension.

#### **7. What if I don't want to take part in this study or if I want to withdraw later?**

Participation in this study is voluntary. It is completely up to you whether or not to participate. If you decide not to participate it will not affect the treatment you receive now or in the future. Whatever your decision it will not affect the relationship with staff caring for you. You may withdraw from the study at any time and for any reason and for no reason. Information that has been collected from you, prior to

your withdrawal, will continue to be used in the data analysis. No new information will be collected or used after you have withdrawn from the study.

**8. How long is my participation needed?**

The participation will be at one point that is one day

**9. What does the study involve?**

This study involves assessing risk factors for OSA in hypertensive patients

**10. What about my confidentiality/privacy?**

This information will be kept confidential and will be used only for scientific reasons and at no point in time the participant's identity will be disclosed during publication. Patient's information will not be shared with any third party except proper authorities.

**11. Will I have to pay for any study related investigations/procedures/treatment?**

No, you don't have to pay for any study related investigations/procedures/treatment

**12. Compensation?**

Participant is not entitled for any compensation monetary or otherwise during and after study is over.

**13. Whom can I contact for further information?**

You can contact principal investigator on the contact information given below.

Principal investigator:

Phone No.

Thank you for taking the time to consider this study. If you wish to take part, please sign the attached consent form.

**This information sheet is for you to keep.**

**CONSENT FORM FOR RESEARCH STUDY**

**TITLE OF PROJECT**

**“Assessing risk factors for obstructive sleep apnea (OSA) in hypertensive patients “**

**Nature of study**

It is a noninvasive study to observe the risk factors for OSA in diagnosed hypertensive patients using STOP BANG questionnaire and assessing the upper airway through an oral examination for Mallampati Score.

**Procedure of study-**

1. Participants need to complete the STOP BANG questionnaire – for which Body Mass Index (BMI) is calculated and Neck Circumference is measured.
2. With all the required precautions and physical distancing patient is asked to open the mouth and from a distance, oral cavity of patient is examined for Mallampati scores

**The results of this study will be presented anonymously without your identity being disclosed.**

**Tick to Confirm**

I confirm that I have read and understood the information sheet Dated day/month/year for the above study

I have had the opportunity to consider the information Ask questions and have had these answers satisfactorily

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care and legal rights being affected

I understand that relevant sections of any data collected during the study, may be viewed by responsible individuals from MGM MEDICAL COLLEGE (IERC) and regulatory authorities, as and when relevant.

I give permission to these individuals to have access to my Records

**I agree to take part in the above research study of my own will**

Name of Participant:

Signature

Name of Investigator:

Signature

Witness Name:

Signature

Date:

Place:

**CASE STUDY FORM**

Participant number:

Date-

**Assessing risk factors for obstructive sleep apnea (OSA) in hypertensive patients**

1. Participant Name-
2. Age-
3. Sex-
4. Address-
5. Contact no-

**History and examination:**

1. Quality of sleep on likert scale of 1-5 (1 being good sleep and 5 poor sleep):
2. Family History of cardiovascular Disease : Yes/No
3. If yes, please specify
4. Blood Pressure as in case sheet :

**1. STOP-BANG score:**

Height:

Weight:

**BMI = kg/m<sup>2</sup>=**

**Neck Circumference:**

Category based on STOP BANG score (Low, Moderate, High risk):

**2. Mallampati Score-**

Class (based on score):

If any other specific information

## STOP-BANG QUESTIONNAIRE

Name : \_\_\_\_\_

Date: \_\_\_\_\_

Age : \_\_\_\_\_

Gender : \_\_\_\_\_

Please answer the following 8 dichotomous (Yes/ No) questions

<u>Sr. No.</u>	<u>Questions</u>	<u>Yes</u>	<u>No</u>
1.	Do you snore loudly?		
2.	Do you often feel tired, fatigued, or sleepy during the daytime?		
3.	Has anyone observed that you stop breathing or choke or gasp during your sleep?		
4.	Do you have or are you being treated for high blood pressure?		
5.	Is your body mass index more than 35 kg/m <sup>2</sup> ?		
6.	Are you older than 50 years?		
7.	Is your neck circumference greater than 40 cm?		
8.	Are you male?		

### STOP-BANG scores-

- 0-2 :- Low risk of OSA
- 3-4 :- Moderate risk of OSA
- $\geq 5$  :- High risk of OSA