

Documents to be submitted to ethics committee for PG dissertation

| S.No | Name of the document | Submitted Yes / No |
|------|--|-----------------------|
| I | <ul style="list-style-type: none"> a. Request letter from Principal Investigator (P.G) to the chairman, Institutional Ethics Committee, Osmania Medical College, Hyderabad, through proper channel. (Annexed) b. Forwarded & signed by Guide & HOD | YES |
| II | Dissertation Protocol (Annexed) <ul style="list-style-type: none"> i. Title of Dissertation ii. Details of Principal Investigator iii. Details of Guide , co – guide & HOD <ul style="list-style-type: none"> ➤ Email ID ➤ Contact Number | YES |
| III | PROFORMA FOR REGISTRATION OF DISSERTATION (Annexed) <ul style="list-style-type: none"> 1. Name of the candidate and address 2. Name of the Institution 3. Course of study and subject 4. Date of admission to course 5. Title of the topic 6. Brief review of the intended work <ul style="list-style-type: none"> ➤ Need for study ➤ Aims ➤ Objectives of the study ➤ Inclusion criteria ➤ Exclusion criteria ➤ Sample size ➤ Duration of the study ➤ Study Design ➤ Materials and Methods ➤ Source of the data ➤ Case sheet Performa & Investigations ➤ Review of literature & References 7. Signature of the candidate 8. Name & signature of Guide 9. Name & signature of HOD 10. Name & signature of the Principal | YES |
| IV | Participant Information Sheet (ANNEXED) | YES |
| V | Informed Consent Form(ANNEXED) | YES |

I (a). Request Letter

Date : 30th October 2018

Place : Koti, Hyderabad

From

Dr. Allu Chandana
First Year P.G.
Department of E.N.T,
Osmania Medical College,
Hyderabad.

To

The Chairman,
Institutional Ethics Committee
Osmania Medical College,
Hyderabad.

Respected Sir,

Through proper Channel

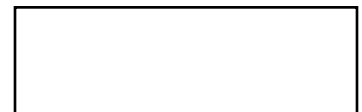
Sub : Request for thesis approval from Institutional Ethics Committee

I, Dr. Allu Chandana, FIRST Year P.G in the Department of E.N.T, would like to submit my thesis protocol for Institutional Ethics Committee's approval. My thesis topic is "**A STUDY OF COMPARISON BETWEEN PRE-OPERATIVE RADIOLOGICAL FINDINGS, DIAGNOSTIC NASAL ENDOSCOPY AND INTRA-OPERATIVE FINDINGS IN PATIENTS WITH CHRONIC RHINO SINUSITIS,**" at tertiary E.N.T hospital.

I have enclosed the protocol herewith. Kindly do the needful.

Thanking you Sir,

Yours faithfully,



DR. ALLU CHANDANA

I (b). Request Letter

Date : 30th October 2018

Place : Koti, Hyderabad

From

Dr. Allu Chandana
First Year P.G.
Department of E.N.T,
Osmania Medical College,
Hyderabad.

To

The Professor and HOD,
Department of E.N.T
Osmania Medical College,
Hyderabad.

Respected Sir,

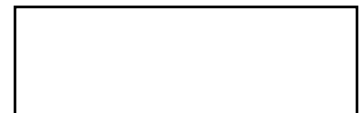
Through proper Channel

Sub: Request for Permission to do my dissertation work at the
Department of E.N.T, Government E.N.T Hospital.

I, Dr. Allu Chandana, FIRST Year P.G in the Department of E.N.T, hereby request you to grant me permission to do my dissertation work in the Department of E.N.T, on the topic "**A STUDY OF COMPARISON BETWEEN PRE-OPERATIVE RADIOLOGICAL FINDINGS, DIAGNOSTIC NASAL ENDOSCOPY AND INTRA-OPERATIVE FINDINGS IN PATIENTS WITH CHRONIC RHINO SINUSITIS,**" at Government E.N.T Hospital.

Thanking you Sir,

Yours faithfully,

A rectangular box intended for the signature of Dr. Allu Chandana.

DR. ALLU CHANDANA

II. Dissertation Protocol

1. TITLE OF DISSERTATION / THESIS TITLE: *A Study of Comparison Between Pre-Operative Radiological Findings, Diagnostic Nasal Endoscopy and Intra-Operative Findings in Patients with Chronic Rhino Sinusitis, at Tertiary ENT Care Hospital*

2. DETAILS OF PRINCIPAL INVESTIGATOR

- | | |
|------------------------|----------------------|
| a. Name | : DR. ALLU CHANDANA |
| b. Designation | : Post Graduate |
| c. Department | : E.N.T |
| d. Phone Number | : (+91) 85 00 287296 |
| e. Registration Number | : TSML / FMR / 03408 |

3. DETAILS OF GUIDE, CO- GUIDE & HOD

- | | |
|-------------------|--|
| Name of the Guide | : DR. L. SUDARSHAN REDDY |
| Designation | : Professor |
| Department | : E.N.T |
| Institution | : Osmania Medical College, Hyderabad |
| Contact Number | : (+91) 80 96 817081 |
| Email – id | : drlsudarshanreddy9@gmail.com |

- | | |
|------------------------|--|
| Name of the Co - Guide | : DR. N. KARUNA |
| Designation | : Associate Professor |
| Department | : E.N.T |
| Institution | : Osmania Medical College, Hyderabad |
| Contact Number | : (+91) 97 01 098505 |
| Email – id | : rayudukaruna@yahoo.co.in |

- | | |
|-----------------|--|
| Name of the HOD | : DR. ANAND ACHARYA |
| Designation | : Professor and HOD |
| Department | : E.N.T |
| Institution | : Osmania Medical College, Hyderabad |
| Contact Number | : (+91) 98 48 038242 |
| Email – id | : acharya.is.anand@gmail.com |

III. Proforma for Registration of Dissertation

| | | |
|----|---|---|
| 1. | NAME OF THE CANDIDATE AND ADDRESS | DR. ALLU CHANDANA |
| 2. | NAME OF THE INSTITUTION | OSMANIA MEDICAL COLLEGE / GENERAL HOSPITAL |
| 3. | COURSE OF STUDY AND SUBJECT | MS (E.N.T) |
| 4. | DATE OF ADMISSION TO COURSE | 18 TH MAY 2018 |
| 5. | TITLE OF THE TOPIC | A STUDY OF COMPARISON BETWEEN PRE-OPERATIVE RADIOLOGICAL FINDINGS, DIAGNOSTIC NASAL ENDOSCOPY AND INTRA-OPERATIVE FINDINGS IN PATIENTS WITH CHRONIC RHINO SINUSITIS |
| 6. | <p>BRIEF REVIEW OF INTENDED WORK</p> <ul style="list-style-type: none"> ➤ Need for study ➤ Aim ➤ Objective | <p>Chronic rhino sinusitis (CRS) is one of the most common chronic diseases. The advent of CT scan and nasal endoscopy in the delineation of the sinonasal pathology and anatomical variations has proven invaluable to the otolaryngologists in the pre-operative planning but are not always accurate in depicting the disease and anatomical variants. These discrepancies though minor, need further evaluation and correlation with that of findings observed during Functional Endoscopic Sinus Surgery.</p> <p>To correlate the pre-operative CT scan and Nasal Endoscopy findings with intra-operative findings in CRS thereby detecting the disparity between them.</p> <ol style="list-style-type: none"> 1. To evaluate the accuracy of objective diagnostic modalities in Chronic Rhino Sinusitis. 2. To delineate the extent of disease, define anatomical variants, relationship of sinuses surrounding important structures. |

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| ➤ Inclusion Criteria | <ol style="list-style-type: none"> 1. All patients with a diagnosis of CRS both male and female above 10 years of age with or without polyposis undergoing endoscopic sinus surgery, after getting an informed consent. 2. All patients who have received treatment with adequate antibiotics, decongestants and a 6-week course of topical steroids, systemic antihistamines and systemic steroids. 3. Preoperative CT scan would be taken after the aforementioned medical treatment. |
| ➤ Exclusion Criteria | <ol style="list-style-type: none"> 1. Those less than 10 years of age 2. Those with other morbidities like diabetes mellitus, malignancy, immunocompromised status; also pregnant women and breast-feeding mothers. 3. Those with a history of nasal and paranasal sinus surgery in the past. 4. Those with histological or radiological documentation of invasive fungal sinusitis. 5. Those who are not compliant with the prescribed medical and surgical treatment. |
| ➤ Sample Size | 100 cases of Chronic Rhino Sinusitis (CRS) |
| ➤ Duration of study | November 2018 – October 2020 |
| ➤ Study Design | Prospective Observational Study |
| ➤ Material & Methods | <p>This is a prospective observational study of 100 patients attending regular ENT outpatient department (OPD) between the period of November 2018 and October 2020. The cases selected for the study were subjected to detailed history taking and ENT examination. Routine investigation viz., CBP, CT, BT, RBS, Blood Urea and CUE were done. All patients in active stage of the disease were treated with course of suitable antibiotics, systemic antihistamines, local decongestants and topical and systemic steroids. Each patient underwent a systematic DNE and CT of nose and para-nasal sinuses after maximum medical therapy. The patients underwent Functional Endoscopic Sinus Surgery after obtaining written informed consent. The CT scan and DNE findings were correlated with Intra-operative Endoscopic findings.</p> |

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| | <p>➤ Source of data</p> <p>➤ Investigations</p> <p>➤ Review of Literature & References</p> | <p>Tertiary E.N.T Care Hospital</p> <p>Viral Screening, Haemoglobin, Complete Blood Count, Coagulation Time ,Bleeding Time, Platelet Count, Urine Examination, CT of Nose and Para-nasal Sinus, Diagnostic Nasal Endoscopy.</p> <ol style="list-style-type: none"> 1. Shrutih Satyanarayana Handanakere, Chidananda Ramappa Devasanudra. Clinical Study of correlation between preoperative CTscan findings with intraoperative findings in cases of chronic rhinosinusitis. <i>Indian Journal of Anatomy & Surgery of Head, Neck & Brain, April-June, 2016;2(2)</i> 49-52. 2. Mallikarjuna S. Tegnoor, Joseph Williams Geogre, Williams George, Ramchandra Joshi. Comparative Study between diagnostic nasal endoscopy and computed tomography of ONS in sino nasal diseases. <i>Internation Journal of Otorhinolaryngology and Head and Neck Surgery, 2017 Oct; 3(4):</i>972-978. 3. Sheetal. D, Devan P P, Manjunath P, Martin P, Satish Kumar K, Sreekantha Satisha T G, Manjunath Goud. CR PNS – Do we really require before fess? <i>Journal of Clinical and Diagnostic Research. 2011 Apr, Vol- 5(2):</i>179-181 4. Bhattacharyya N. Clinical and symptom criteria for the accurate diagnosis chronic rhinosinusitis. <i>Laryngoscope 2006;116(7 Suppl 110)(Pt 2).</i> 5. Deepthi NV, Menon UK, Menon IR. Correlations and Comparison between Repeat Computed Tomography Scores, Endoscopy Scores and Symptomatic Improvement before and after Endoscopic Sinus Surgery: A Pilot Study. <i>Clin Rhinol An Int J 2013;6(1):</i>32-40. 6. Deosthale NV. Diagnostic Accuracy of Nasal Endoscopy as Compared to Computed Tomography in Chronic Rhinosinusitis. <i>Indian J Otolaryngol Head Neck Surg. 2017 Dec;69(4):</i>494-499. |
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|-----|---------------------------------|--|
| | | <p>7. Wabnitz DA, Nair S, Wormald PJ. Correlation between preoperative symptom scores, quality-of-life questionnaires, and staging with computed tomography in patients with chronic rhinosinusitis. <i>Am J Rhinol</i> 2005;19:91-96.</p> <p>8. Ryan WR, Ramachandra T, Hwang PH. Correlations between symptoms, nasal endoscopy, and in-office computed tomography in postsurgical chronic rhinosinusitis patients. <i>Laryngoscope</i> 2011;121:674-78.</p> |
| 7. | SIGNATURE OF CANDIDATE | <u>DR. ALLU CHANDANA</u> |
| 8. | NAME AND SIGNATURE OF GUIDE | <u>DR. L. SUDARSHAN REDDY</u> |
| 9. | NAME AND SIGNATURE OF HOD | <u>DR. ANAND ACHARYA</u> |
| 10. | NAME AND SIGNATURE OF PRINCIPAL | <u>DR. P. SASHIKALA REDDY</u> |

IV. Participant Information Sheet

PROTOCOL TITLE : *A Study of Comparison between Pre-operative Radiological Findings, Diagnostic Nasal Endoscopy and Intra-operative Findings in Patients with Chronic Rhino Sinusitis, at Tertiary ENT Care Hospital*

PRINCIPAL INVESTIGATOR : DR. ALLU CHANDANA

DESIGNATION : M.S. (E.N.T)

HOSPITAL : GOVERNMENT E.N.T HOSPITAL / OSMANIA MEDICAL COLLEGE

CONTACT NUMBER : (+91) 85 00 287296

PLEASE READ THIS INFORMATION CAREFULLY. IF YOU DON'T UNDERSTAND THE LANGUAGE OR ANY INFORMATION IN THIS DOCUMENT, PLEASE DISCUSS WITH THE STUDY DOCTOR. IF YOU DECIDE TO VOLUNTEER TO THIS STUDY YOU MUST SIGN AT THE END OF THIS FORM.

INTRODUCTION TO THE RESEARCH STUDY : You are being asked to take part in this study because you have Chronic Rhino Sinusitis (CRS)

PURPOSE OF STUDY : To correlate the pre-operative CT scan and Nasal Endoscopy findings with intra-operative findings in CRS thereby detecting the disparity between them.

WHO CAN TAKE PART : All patients with Chronic Rhino Sinusitis (CRS) above 10 years of age.

WHAT WILL HAPPEN DURING STUDY :

1. All patients with Chronic Rhino Sinusitis (CRS) will be evaluated.
2. Physical Examination of these patients will be done.
3. Management of patients will be done with CT scan, Nasal Endoscopy, Functional Endoscopic Sinus Surgery & required investigations will be done.
4. Any questionnaire (may) given must/will be duly filled.

Your role/responsibility in the study: Role of the subject during the study:

- Provide accurate information whenever asked.
- Must inform the study doctor about any problem experienced during the study.
- Follow the investigators instruction.
- If you want to discontinue from the study, study doctor to be informed.

What are the potential benefits of participating in the study:

You may or may not get benefit from participating in this study. It is possible that you may get better, stay the same, or get worse. If you take part in this study you may help other patients with Chronic Rhino Sinusitis (CRS) by contributing to the knowledge on this disease process.

Compensation for injury:

If a medical problem arises during this research as a direct result of the treatment done for the study, the study doctor will be responsible for making sure that proper medical care is provided to you, if you suffer any physical/mental injury or illness as a direct result of the proper administration of the study drug to you or of properly performed study procedures.

Confidentiality of information:

Information from the study including your name, address, medical records, results of tests, study results will be reviewed only by authorized personnel from the sponsor or their representative, Ethics committee or regulatory bodies. Information and results from this study may be presented at meetings or published in journals without including your name and personal identifications.

New information about the study:

Any new information available during the course of the study will be informed to you if it has relevance to your decision regarding continuing in the study.

Voluntary participation:

Entering a research study is voluntary. If you volunteer for a research study, you have the right to stop at any time and you need not give any reason for the same. Your decision not to participate in the study will not affect your future treatment. The investigator may stop the research or your participation in it at any time for some or other reason without your permission.

V. Informed Consent Form

Patient Identification Number :
Title of the Project : *A Study of Comparison between Pre-operative Radiological Findings, Diagnostic Nasal Endoscopy and Intra-operative Findings in Patients with Chronic Rhinosinusitis, at Tertiary ENT Care Hospital*
Name of the Principal Investigator : DR. ALLU CHANDANA
Contact Number : (+91) 85 00 287296

The contents of the information sheet provided have been read carefully by me/explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions. The nature and purpose of the study and its potential risks/ benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. 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 or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from Osmania medical college or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

In case if the patient is minor (less than 18 years of age), as parent on his/her behalf, I agree to my child taking part in the above study.

Date:

(Signature / left thumb impression)

Place : _____

Name of the Participant: _____

S/o | D/o : _____

Complete Address : _____

This is to certify that the above consent has been obtained in my presence.

Date:

(Signature / left thumb impression of witness)

Place : _____

Name : _____

Address : _____

V. सूचित सहमति प्रपत्र

रोगी पहचान संख्या :
प्रोजेक्ट का शीर्षक : *A Study of Comparison between Pre-operative Radiological Findings, Diagnostic Nasal Endoscopy and Intra-operative Findings in Patients with Chronic Rhinosinusitis, at Tertiary ENT Care Hospital*
प्रधान अन्वेषक का नाम : DR. ALLU CHANDANA
संपर्क नंबर : (+91) 85 00 287296

सूचना पत्रक की सामग्री प्रदान की गई है मेरे द्वारा ध्यान से पढ़ा/विस्तार से मुझे समझाया, एक भाषा है कि मैं समझ में, और मैं पूरी तरह से सामग्री समझ है। मैं पुष्टि करता हूँ कि मुझे सवाल पूछने का मौका मिला है। अध्ययन की प्रकृति और उद्देश्य और उसके संभावित जोखिम/लाभ और अध्ययन की उम्मीद की अवधि, और अध्ययन के अंत्य प्रासंगिक विवरण मुझे विस्तार से समझाया गया है। मैं समझता हूँ कि मेरी भागीदारी स्वैच्छिक है और है कि मैं किसी भी समय वापस लेने के लिए स्वतंत्र हूँ, किसी भी कारण देने के बिना, मेरी चिकित्सा देखभाल या कानूनी अधिकार के बिना प्रभावित किया जा रहा है।

मैं समझता हूँ कि इस अनुसंधान और मेरे मेडिकल नोटों में से किसी के वर्गों में अपनी भागीदारी से मेरे बारे में एकत्र जानकारी उस्मानिया मेडिकल कॉलेज से जिम्मेदार व्यक्तियों या विनियामक अधिकारियों से देखा जा सकता है जहां यह मेरे लिए प्रासंगिक है अनुसंधान में भाग ले रहे हैं। मैं इन व्यक्तियों के लिए अनुमति देने के लिए अपने रिकॉर्ड तक पहुंच है।

मामले में यदि रोगी नाबालिग है (18 वर्ष से कम आयु), उसकी/उसकी ओर से माता पिता के रूप में, मैं अपने बच्चे को ऊपर अध्ययन में भाग लेने के लिए सहमत हूँ।

Date:

(Signature / left thumb impression)

Place : _____

Name of the Participant: _____

S/o | D/o : _____

Complete Address : _____

This is to certify that the above consent has been obtained in my presence.

Date:

(Signature / left thumb impression of witness)

Place : _____

Name : _____

Address : _____

V. తెలియజేసిన సమ్మతి పత్రం

రోగి గుర్తింపు సంఖ్య

:

ఈ ప్రాజెక్టు టైటిల్

: A Study of Comparison between Pre-operative

Radiological Findings, Diagnostic Nasal Endoscopy and
Intra-operative Findings in Patients with Chronic Rhino
Sinusitis, at Tertiary ENT Care Hospital

ప్రధాన పరిశోధకుడు పేరు

: DR. ALLU CHANDANA

సంప్రదింపు సంఖ్య

: (+91) 85 00 287296

సమాచార పత్రం అందించిన విషయాలు నా ద్వారా జాగ్రత్తగా చదివాను/నాకు వివరంగా వివరించారు, నాకు సంబంధించిన ఒక భాషలో, నేను విషయాలను పూర్తిగా అర్థం చేసుకున్నాను. నేను ప్రశ్నలు అడిగే అవకాశం ఉందని నిర్ధారించండి. అధ్యయనం యొక్క స్వభావం మరియు ప్రయోజనం మరియు దాని సంభావ్య ప్రమాదాలు/ప్రయోజనాలు మరియు అధ్యయనం యొక్క ఊహించిన వ్యవధి, మరియు అధ్యయనం యొక్క ఇతర సంబంధిత వివరాలు నాకు వివరంగా వివరించారు. నా వైద్య సంరక్షణ లేదా చట్టపరమైన హక్కు ప్రభావితం లేకుండా, ఏ కారణం ఇవ్వకుండా, నేను ఏ సమయంలోనైనా, నేను ఖాళీ అని నా పాల్గొనడం స్వచ్ఛంగా ఉందని అర్థం.

నేను ఈ పరిశోధన మరియు నా వైద్య గమనికలు ఏ నా భాగస్వామ్యం నుండి నా గురించి సేకరించిన సమాచారం నేను అర్థం ఉండవచ్చు ఉస్మానియా వైద్య కళాశాల నుండి బాధ్యతగల వ్యక్తులు లేదా నియంత్రణా అధికారుల నుండి నా పరిశోధనలో భాగంగా. నా రికార్డులను ప్రాప్యత చేయడానికి ఈ వ్యక్తులకు నేను అనుమతి ఇస్తాను.

ఒకవేళ రోగి మైనర్ (18 సంవత్సరాల కంటే తక్కువ వయస్సు) ఉంటే, అతని/ఆమె తరపున తల్లిదండ్రులు, పై అధ్యయనంలో భాగంగా నా బిడ్డకు నేను అంగీకరిస్తున్నాను.

Date:

(Signature / left thumb impression)

Place : _____

Name of the Participant: _____

S/o | D/o : _____

Complete Address : _____

This is to certify that the above consent has been obtained in my presence.

Date:

(Signature / left thumb impression of witness)

Place : _____

Name : _____

Address : _____

فارم کا رضامندی باخبر V.

نمبر شناختی مریض
خطاب کا منصوبہ اس

:
: A Study of Comparison between Pre-operative
Radiological Findings, Diagnostic Nasal Endoscopy and
Intra-operative Findings in Patients with Chronic Rhino
Sinusitis
: DR. ALLU CHANDANA
: (+91) 85 00 287296

نام کا کار تفتیش پرنسپل
کریں رابطہ سے نمبر

میں، بزبان میں زبان ایک مجھے میں تفصیل / مطالعہ بغور سے طرف میری کیا کی مشمولات کے ورق کے معلومات کردہ فراہم مقصد اور نوعیت۔ ہے ملا موقع کا کرنے سوالات میں کہ کریں تصدیق میں۔ کی وضاحت نے ہے سمجھ پر طور مکمل کو مشمولات مجھ مستغنی سے گیا کیا مطالعہ کا تفصیلات متعلقہ دیگر اور مدت متوقع کی مطالعہ اور فوائد / خطرات ممکنہ کے اس اور مطالعہ کا، بغیر کے دینے وجہ کسی، وقت بھی کسی میں کہ یہ اور ہے عمل رضاکارانہ شرکت میری کہ ہوں سمجھتا میں۔ ہے میں تفصیل سے۔ ہوں آزاد لیے کے لینے واپس بغیر کے ہونے متاثر حق قانونی یا بھال دیکھ طبی میری

کسی سے میں نوٹس طبی میری اور سے شمولیت میری میں تحقیق اس میں بارے میرے گئی کی جمع معلومات کہ سمجھتا یہ میں میں تحقیق میری ہے متعلق سے اس جہاں سے کالج میڈیکل عثمانیہ اتھارٹیز انضباطی یا افراد دار ذمہ سے طرف کی نگاہ ہو ہو حصے۔ ہے دیتا اجازت کی لئے کے کرنے حاصل رسائی تک ریکارڈ اپنے کو افراد ان میں۔ ہے رہا لے حصہ

حصہ میں تحقیق بالا مندرجہ بچہ میرا میں، ہے معمولی پر طور کے والدین سے طرف اپنی، (عمر کی سال 18 کم سے کم) مریض اگر میں صورت کی اتفاق لئے کے لینے

Date:

(Signature / left thumb impression)

Place : _____
Name of the Participant: _____
S/o | D/o : _____
Complete Address : _____

This is to certify that the above consent has been obtained in my presence.

Date:

(Signature / left thumb impression of witness)

Place : _____
Name : _____
Address : _____
