From ,
Dr. Dipti Parmar
1st Year Resident
Department of Radio-diagnosis Parul Institute of Medical Sciences & Research (PIMSR), Limda.
E Mail: dp291198@gmail.com
Mobile No: 7990873918
Date: 12/08/2024

To,

Parul University Institutional Ethics Committee for Human Research (PUIECHR), Parul Institute of Medical Sciences & Research (PIMSR).
Limda, Gujarat, India.

Subject: Application for getting permission to carry out research work as a M.D.(Radio-diagnosis) PG Resident

Sir/Madam,

I, undersigned **Dr. Dipti Parmar,** currently working as a 1st Year Resident in Department of Radio-diagnosis Faculty of Medicine under Parul Institute of Medical Sciences & Research (PIMSR). I am applying for M.D. Dissertation permission in the Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR), Limda. I want to carry out research study entitled **"Role of High Resolution Computed Tomography [HRCT] of Temporal Bone In Evaluation Of Middle Ear Diseases and Its Correlation With Intra Operative Findings"** Under guidance of **Dr. Dharmesh Baria**, Associate Professor in department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR), Limda.

I am submitting proposal for the study in the prescribed format along with necessary reference papers, and assurance letter from the guide. This Study will be conducted strictly as per the ethical guidelines with due consideration of prevention of plagiarism.

Thanking You,

Yours Sincerely,

Dr. Dipti Parmar

Enclosures

1. Application Form
2. Assurance Letter of Guide
3. Study Protocol with Study Related Documents
4. Case Report Form, Patient Information Sheet & Informed Consent Form.
5. Permission of Dean, Parul Institute of Medical Sciences & Research (PIMSR) Limda.
6. Permission of Medical Superintendent, Parul Sevashram Hospital, Limda.
7. Minutes of Presentation at Department Meeting with Signed Attendance Sheet

Forwarded through Head of the Department

APPLICATION FORM

Title of The Study	**"Role of High Resolution Computed Tomography [HRCT] of Temporal Bone In Evaluation Of Middle Ear Diseases and Its Correlation With Intra Operative Findings"**
Name of The Student	**Dr. Dipti Parmar** **M.B.B.S.**
PG Admission Month and Year Branch Name	**e.g. October2023** **M.D.(Radio-diagnosis)**
Name of the Guide & Department	**Dr. Dharmesh Baria** **Designation: - Associate Professor** **Department of Radiodiagnosis,** **Parul Institute of Medical Sciences & Research.**
Source of funding if any	**No**
Type of Study	**Cross sectional observational study**
Ethical Issues Involved In The Study	**_____** **Invasive Procedure: no**
ProposalEnclosedIn8Copies.	**Yes**
Whether Consent Forms In English & Vernacular Language is Enclosed.	**Yes**
Is this special research?	**Animal Experiment: No** **Clinical Trial: No** **Research on Patented Product: No** **Research on Herbal Extract: No**

Signature of the PG Resident:
Dr. Dipti Parmar

Signature of the guide:
Dr. Dharmesh Baria

From:
Dr Dipti Parmar
1st Year Resident
Department of Radio-diagnosis
Parul Institute of Medical Sciences
& Research(PIMSR) Limda.
Date: 12/08/2024

To,
The Dean,

Parul Institute of Medical Sciences & Research (PIMSR), Limda,
Gujarat, India.

Subject: **Application for getting permission to carry out research work as a M.D. (Radio-diagnosis) PG Student**

Respected Sir,

I, undersigned **Dr. Dipti Parmar,** applying for study in the Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR.I want to carry out research study entitled "**Role of High Resolution Computed Tomography [HRCT] of Temporal Bone In Evaluation Of Middle Ear Diseases and Its Correlation With Intra Operative Findings**" under guidance of **Dr. Dharmesh Baria** Associate Professor in Department of Radio diagnosis, Parul Institute of Medical Sciences & Research (PIMSR), Limda. Kindly give me permission to carry out above mentioned research work.

Thanking You,

Yours Sincerely,

Dr. Dipti Parmar

From:
Dr. Dipti Parmar
Department of Radio-diagnosis
Parul Institute of Medical
Sciences & Research
(PIMSR) Limda.
Date: 12/ 08 /2024

To,
The Medical Superintendent,

PSH & Parul Institute of Medical Sciences & Research (PIMSR), Limda,
Gujarat, India.

Subject: **Application for getting permission to carry out research work as a M.D. (Radio-diagnosis) PG Resident**

Respected Sir/Madam,

I, undersigned **Dr. Dipti Parmar** applying for study in the Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research. I want to carry out research study entitled **"Role of High Resolution Computed Tomography [HRCT] of Temporal Bone In Evaluation Of Middle Ear Diseases and Its Correlation With Intra Operative Findings"** under guidance of **Dr. Dharmesh Baria** Associate Professor in Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR), Limda.

Kindly give me permission to carry out above mentioned research work.

Thanking You,

Yours Sincerely,

Dr. Dipti Parmar

Date: 12/ 08 /2024

To,

Parul University Institutional Ethics Committee for Human Research (PUIECHR), Parul Institute of Medical Sciences & Research (PIMSR), Limda.

Subject: **Assurance for mentoring of Dr. Dipti Parmar for M.D. Study in Department of Radio-diagnosis.**

Sir/Madam,

This is to inform you that the research work entitled **"Role of High Resolution Computed Tomography [HRCT] of Temporal Bone In Evaluation Of Middle Ear Diseases and Its Correlation With Intra Operative Findings"** will be carried out by **Dr. Dipti Parmar** in the Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR) Limda, under our guidance and observation.

We assure you in this regard that the work will be done strictly as per the ethical guidelines with due consideration of prevention of plagiarism.

Yours Truly,

Dr. Anil Rathva
Designation: -Professor and Head of department
Department of Radio-diagnosis
Parul Institute of Medical Sciences & Research (PIMSR), Limda

Study Protocol

NAME OF THE RESEARCHER

Dr. Dipti Parmar (M.B.B.S.)

Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR) Limda.

NAME OF THE GUIDE AND DEPARTMENT

Dr. Dharmesh Baria, Designation: Associate Professor

Department of Radio-diagnosis, Parul Institute of Medical Sciences & Research (PIMSR) Limda.

TITLE OF THE STUDY

"Role of High Resolution Computed Tomography [HRCT] of Temporal Bone In Evaluation Of Middle Ear Diseases and Its Correlation With Intra Operative Findings"

INTRODUCTION

The temporal bone is situated on the lower part of the cranial base and comprised of five bones, which are squamous, petrous, mastoid, tympanic and styloid processes. The middle and inner ear are two of the most important ear components located inside the temporal bone. [1]

The middle ear is an air-filled cavity within the petrous portion of the temporal bone that contains the ossicular chain. It is bounded laterally by the tympanic membrane, medially by the inner ear structures (which include the otic capsule and the cochlear promontory), superiorly by the tegmen tympani, and inferiorly by the jugular wall (floor).[11]

Middle ear diseases are defined as diseases restricted to the middle ear cleft which includes the middle ear cavity, mastoid, and the eustachian tube. [4]

Cholesteatoma is a potentially serious condition because it can progressively enlarge and erode into neighboring structures, causing bony destruction, hearing loss, and severe extracranial and intracranial complications such as facial nerve paralysis, labyrinthine fistula, brain abscess, and meningitis. It is more often acquired than congenital, recognized clinically and radiologically.[3]

Chronic otitis media (COM), which causes hearing loss, remains an important public health issue in terms of prevalence, economics, and consequences. Short and long-term effects of otitis media can be disastrous, but they can be considered preventable if diagnosed early and treated effectively, including early surgical intervention to limit the disease. The existence, location, and extent of the disease, as well as the presence of any complications determine the surgical approach to be followed. As a result, imaging is critical in providing valuable information to the surgeon. [8]

Earlier, the majority of temporal bone diseases were detected only through clinical examination. However, with an increase in the prevalence of infective diseases of the ear, it was proposed that the current treatment and prevention strategy was inadequate. As a result, imaging is crucial, especially in complex and recurring instances where the results of the imaging may have a substantial impact on the course of treatment. [5]

Radiological diagnosis of middle ear inflammatory diseases is challenging and necessitates a thorough understanding of anatomy. High-resolution computed tomography (HRCT) excels in evaluating middle ear disease processes and adjacent bone, and its implementation has considerably revolutionized radiological imaging's role in the preoperative detection of middle ear illness and structures.[13] HRCT

is especially useful in detecting early erosive changes in the ossicles, as well as non-dependent soft tissue opacification suggestive of cholesteatoma.[10]

The research establishes the importance of HRCT of the temporal bone as a critical diagnostic tool, providing valuable insights that correlate closely with intraoperative findings, thereby enhancing the accuracy and effectiveness and improve diagnostic precision and surgical outcomes of middle ear disease management.

RATIONALE AND GOAL OF THE STUDY

- HRCT will be helpful to confirm the clinical diagnosis and to provide a more thorough pre-operative evaluation.
- This will enable a better understanding of the etiology, pathology, disease extent and disease progression, which will aid in refining surgical planning, improving patient outcome and early diagnosis of complications.

AIMS

"To Correlate HRCT Temporal Bone imaging finding with Intra Operative Findings For Middle Ear Diseases"

OBJECTIVES

1. To correlate the HRCT temporal bone findings with intra operative findings.
2. To determine the sensitivity and specificity of HRCT for detecting various middle ear pathologies.
3. To describe the spectrum of imaging finding for various middle ear pathologies.

ETHICS COMMITTEE PERMISSION

After getting permission from The Parul University Institutional Ethics Committee for Human Research (PUIECHR) to carry out this study, first patient will be enrolled and study will be carried out.

METHOD AND METHODOLOGY

- This cross sectional observational study will be carried out in the Department of Radio-diagnosis at our institute (Parul sevashram hospital), after obtaining approval from the institutional ethical committee and getting informed and written consent from all the participants in a language best understood by them.
- Patients referred to radiology department of Parul sevashram hospital with newly suspected middle ear diseases will be included.
- HRCT temporal bone will be performed for the included patients.

Acquisition technique

HRCT imaging will be performed using a Alexion 16 (TOSHIBA) 16 slice CT scanner. We perform a helical acquisition. Our pitch is set to 0.8 -1.2 and rotation time of 0.75sec. Speed is 1 mm/ 0.75s. Scan field of view is set to head. Our protocol suggests Kilovolt peak and tube current of 120 kV and 150 effective mAs for acquiring HRCT temporal bone.

For the axial technique, the patient is placed supine and positioned to minimize radiation to the lens. The scan is then planned for acquisition from the lateral scout topogram from the arcuate eminence through the mastoid tip. To limit distortion of reformatted images, axial CT source images may be obtained with a 0° gantry tilt and scan plane parallel to the inferior orbitomeatal line. For best quality of reformatted images in the coronal or sagittal planes, reconstruction of the raw data with submillimeter overlapping sections should be performed. [1]

Image Post Processing:
Standard reconstruction of the original images will be carried out for all included cases. The reconstructed images will have a layer thickness of 0.5 mm and an interval of 0.75 sec. All images should be reconstructed into magnified axial, sagittal, and coronal images in bone algorithm.
Image analysis:
All images will be analyzed using an OSIRIX MD workstation. The axial, sagittal, and coronal images of temporal bone will be observed by radiologist and lesion site, bone destruction, erosions and extent will be recorded.
All images should be reconstructed in bone algorithm.

Study Site

Patients refer to the radiology department of Parul Institute of Medical Sciences & Research (PIMSR), P.O. Limda, Waghodia, Vadodara, Gujarat.

Study Duration:

From the date of approval by ethics committee till 1 years.

Study Design:

Cross sectional observational study

Sample Size:
(**Convenient sampling)**

- As per data,
- Approximately 5 to 6 HRCT temporal bone study are performed per month in the radiology department of Parul Sevashram hospital from which number of surgery performed per month for middle ear pathologies are 3 to 4.
  According to this data sample size will be 45 to 50. (in 1 year).

Inclusion Criteria

1. All patients with newly suspected middle ear diseases referred to the radiology department for HRCT temporal bone evaluation irrespective of age/sex who will undergo for surgical intervention.

Exclusion Criteria

1. Patients with previous operative history of temporal bone.
2. Patients with trauma,
3. Patient not undergoing surgical intervention.

Proposed Advantage of This Study

- By correlating HRCT findings with intraoperative observations, the study can validate the utility and reliability of HRCT as a diagnostic tool for middle ear pathology, helping to refine imaging protocols and improve clinical practice.
- We will be able to understand the reliability of HRCT temporal bone as pre-operative imaging tool.
- We will have better understanding of limitations and pitfalls.

Ethical Consideration:

After getting ethical clearance certificate we will include patients with newly suspected middle ear diseases for which they refer to department of radio-diagnosis for HRCT temporal bone evaluation (patient who will follow inclusion criteria):

Consent: Informed written consent will be taken after persuading the participants about the possible benefits and implications of the study.

Confidentiality: Strict confidentiality of the personal details and information related to the study will be maintained at all level.

Statistical Analysis: All the statistical analysis will be done with IBM SPSS 25 version statistical software package.
For descriptive statistics: frequency distribution, charts, diagrams, percentage & ROC curve will be used.

Potential Risk and benefit involved: There is no potential risks are involved in the under taken study.

References:

1. Ferriastuti W, Ramayuda IB. RADIOLOGICAL ASPECTS OF HR-CT SCAN ON TEMPORAL BONE. Folia Medica Indonesiana (2355-8393). 2022 Mar 1;58(1).
2. Chaudhary SK, Chaudhary M. TO INVESTIGATE THE ASSOCIATION BETWEEN PREOPERATIVE HIGH RESOLUTION COMPUTED TOMOGRAPHY OF THE TEMPORAL BONE AND INTRAOPERATIVE SURGICAL OBSERVATIONS. Int J Acad Med Pharm. 2021;3(1):105-9.
3. Manik S, Dabholkar Y, Bhalekar S, Velankar H, Chordia N, Saberwal A. Sensitivity and specificity of high-resolution computed tomography (HRCT) of temporal bone in diagnosing cholesteatoma and its correlation with intraoperative findings. Indian Journal of Otolaryngology and Head & Neck Surgery. 2021 Mar;73:25-9.
4. Jose J, George UB, Varghese A, Rathore S. Correlation between high-resolution computed tomography temporal bone findings and surgical findings in patients with inflammatory diseases of the middle ear. CHRISMED Journal of Health and Research. 2019 Jul 1;6(3):140-5.
5. Sankhla AK, Dubey N. Assessment of temporal bone diseases by high resolution computed tomography–institution based study. International Journal of Contemporary Medicine Surgery and Radiology. 2019;4(2):B87-90.
6. Jose, Jeslean; George, Uttam B.[1]; Varghese, Ashish[2]; Rathore, Shubhra[1,]. Correlation between High-Resolution Computed Tomography Temporal Bone Findings and Surgical Findings in Patients with Inflammatory Diseases of the Middle Ear. CHRISMED Journal of Health and Research 6(3):p 140-145, Jul–Sep 2019. | DOI: 10.4103/cjhr.cjhr_161_18
7. Prem Kumar Chidambaram, Vivil Vidya Rajkumar R, Vinayagam S, Senthil Kumar Aiyappan, Bulabai Karpagam. High resolution CT imaging in pathologies of temporal bone. International Journal of Contemporary Medicine Surgery and Radiology. 2019;4(3):C11-C17.
8. Aljehani M, Alhussini R. The correlation between preoperative findings of high-resolution computed tomography (HRCT) and intraoperative findings of chronic otitis media (COM). Clinical Medicine Insights: Ear, Nose and Throat. 2019 Aug;12:1179550619870471.
9. Thukral CL, Singh A, Singh S, Sood AS, Singh K. Role of high resolution computed tomography in evaluation of pathologies of temporal bone. Journal of clinical and diagnostic research: JCDR. 2015;9(9):TC07.
10. Chen JY, Mafee MF. Computed tomography imaging technique and normal computed tomography anatomy of the temporal bone. Operative Techniques in Otolaryngology-Head and Neck Surgery. 2014 Mar 1;25(1):3-12.

11. Gomaa MA, Karim AR, Ghany HS, Elhiny AA, Sadek AA. Evaluation of temporal bone cholesteatoma and the correlation between high resolution computed tomography and surgical finding. Clinical Medicine Insights: Ear, Nose and Throat. 2013 Jan;6:CMENT-S10681.

12. Anbarasu A, Chandrasekaran K, Balakrishnan S. Soft tissue attenuation in middle ear on HRCT: Pictorial review. Indian Journal of Radiology and Imaging. 2012 Oct;22(04):298-304.

Case Report Form:

Study Title:

"Role of High Resolution Computed Tomography [HRCT] of Temporal Bone In Evaluation Of Middle Ear Diseases and Its Correlation With Intra Operative Findings"

Patient Information:

Section 1: Patient Information

Name of Patient:	Age/Gender:
Date of admission: (DD/MM/YY)	Patient ID:
Address & Phone no:	

Section 2: Clinical History

1. **Presenting Symptoms:**

COMPLAINT	**YES/NO**	**DURATION**
1. Ear pain		
2. Ear discharge		
3. Hearing loss		
4. Fever		
5. Headache		
6. Vertigo		
7. Tinnitus		

- Past Medical History:

Section 3: Imaging and Intra Operative Findings

1. HRCT Findings:

Middle Ear Pathology Detected on HRCT:

- Cholesteatoma
- Chronic suppurative otits media
- Otosclerosis
- Congenital pathologies of temporal bone
- Other (Specify):

Description of HRCT Findings:

Date of HRCT temporal bone performed:

➢ **Gender - Male / Female**	
➢ **Ear involve - Right / left**	
➢ **Part involve - epitympanum / mesotympanum / hypotympanum**	
➢ **Structure erosion / dehiscence**	
1. Ear ossicles - Malleus / incus / stapes	
2. Scutum	
3. Additus ad antrum	
4. Mastoid air cells	
5. Semicircular canal	
6. Bony facial canal	
7. Facial recess	
8. Sinus tympani	
9. Cochlea	
10. Vestibule	

2. Intra Opertive Findings:

Date of surgery performed:

➢ **Structure erosion / dehiscence**	
1. Ear ossicles - Malleus / incus / stapes	
2. Scutum	
3. Additus ad antrum	
4. Mastoid air cells	
5. Semicircular canal	
6. Bony facial canal	
7. Facial recess	
8. Sinus tympani	
9. Cochlea	
10. Vestibule	

Final Diagnosis:

Information Sheet:

Invitation to participate

We would like to invite you to take part in this research study by completing a survey. Before you decide whether or not to take part, please take time to read the following information which explains why this research is being done and what you involvement would consist of. Talk to others if you wish and please feel free to ask questions if there is anything that you are unsure of. Thank you for reading this.

What is the purpose of the study?

This dissertation aims to explore role of HRCT temporal bone for middle pathologies and correlating the HRCT findings with intraoperative findings. The Radiological examination of the temporal bone is challenging due to the middle and inner ear's complex anatomical nature. HRCT algorithms provides an excellent resolution for Identifying the precise location and extent of abnormalities within the temporal bone and correlating them with intraoperative observations.

It shows concealed areas of the middle ear, such as the sinus tympani and facial recess. This enables a better understanding of the etiology, pathology, and disease progression, as well as the early diagnosis of complications. This has resulted in a decrease in morbidity associated with temporal bone lesions.

Why have I been chosen to take part?

Because you are one who fulfill my inclusion criteria for this study.

Do I have to take part?

No, taking part in this study is voluntary. It is up to you to decide whether or not to take part.

How do I take part?

Just by giving informed consent for the same.

Confidentiality?

All of the data we collect will be kept strictly confidential. The information you give us in the survey will be entered into an anonymized database which will not contain any personal details about you. The study will be carried out in full compliance with all relevant guidance from the ethics committee.

What are the possible problems and disadvantages of taking part?

We do not anticipate any problems arising from participation in this study.

What are the possible benefits of taking part?

HRCT will be helpful to confirm the clinical diagnosis and to provide a more thorough pre-operative evaluation. This enables a better understanding of the etiology, pathology, disease extent and disease progression, as well as the early diagnosis of complications, which results in in a decrease in morbidity associated with temporal bone lesions.

Who has reviewed the study?

The study has been reviewed by the Research Ethics Committee.

What if there is a problem?

if you wish to complain ,or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should contact Dr. Dipti Parmar (7990873918 / dp@291198@gmail.com)

रोगी सूचना पत्रक:

भाग लेने हेतु आमंत्रण

हम आपको एक सर्वेक्षण पूरा करके इस शोध अध्ययन में भाग लेने के लिए आमंत्रित करना चाहते हैं। इससे पहले कि आप निर्णय लें कि भाग लेना है या नहीं, कृपया निम्नलिखित जानकारी को पढ़ने के लिए समय निकालें जो बताती है कि यह शोध क्यों किया जा रहा है और इसमें आपकी भागीदारी क्या होगी। यदि आप चाहें तो दूसरों से बात करें, और यदि कोई ऐसी बात हो जिसके बारे में आप अनिश्चित हों तो कृपया बेझिझक प्रश्न पूछें का। इसे पढ़ने के लिए आपका धन्यवाद।

अध्ययन का उद्देश्य क्या है?

इस अध्ययन का उद्देश्य कनपटी की हड्डी की विकृति के लिए एचआरसीटी की सटीकता का पता लगाना और इंट्राऑपरेटिव निष्कर्षों के साथ एचआरसीटी निष्कर्षों को सहसंबंधित करना है। मध्य और आंतरिक कान की जटिल शारीरिक संरचना के कारण टेम्पोरल हड्डी का रेडियोलॉजिकल मूल्यांकन मुश्किल है। एचआरसीटी एल्गोरिदम कनपटी की हड्डी के भीतर विकृति के सटीक स्थान और सीमा की पहचान करने और उन्हें इंट्राऑपरेटिव टिप्पणियों के साथ सहसंबंधित करने के लिए एक उत्कृष्ट संकल्प प्रदान करता है।

यह मध्य कान के छिपे हुए क्षेत्रों को दिखाता है,जिसमें साइनस टिम्पनी और फेशियल रिसेस शामिल हैं। इससे बीमारी के कारणों, विकृति विज्ञान और रोग उत्पत्ति की बेहतर समझ हो सकती है, साथ ही जटिलताओं का शीघ्र पता लगाया जा सकता है। जिस से रोगिष्टता कम हो सकती है।

मुझे भाग लेने के लिए क्यों चुना गया है?

क्योंकि आप उनमें से हैं जो इस अध्ययन के लिए मेरे समावेशन मानदंडों को पूरा करते हैं।

क्या मुझे भाग लेना होगा?

नहीं, इस अध्ययन में भाग लेना स्वैच्छिक है। इसमें भाग लेना है या नहीं यह निर्णय लेना आपके ऊपर है।

मैं कैसे भाग ले सकता हूँ?

बस इसके लिए सूचित सहमति देकर।

गोपनीयता?

हमारे द्वारा एकत्र किए गए सभी डेटा को पूरी तरह से गोपनीय रखा जाएगा। सर्वेक्षण में आप हमें जो जानकारी देंगे उसे एक अज्ञात डेटाबेस में दर्ज किया जाएगा जिसमें आपके बारे में कोई व्यक्तिगत विवरण नहीं होगा। अध्ययन नैतिकता समिति के सभी प्रासंगिक दिशानिर्देशों के पूर्ण अनुपालन में किया जाएगा।

भाग लेने की संभावित समस्याएँ और नुकसान क्या हैं?

हमें इस अध्ययन में भाग लेने से उत्पन्न होने वाली किसी भी समस्या की आशा नहीं है।

भाग लेने के संभावित लाभ क्या हैं?

एचआरसीटी नैदानिक निदान की पुष्टि करने और अधिक गहन प्री-ऑपरेटिव मूल्यांकन प्रदान करने में सहायक होंगे।

इससे बीमारी के कारणों, विकृति विज्ञान और रोग उत्पत्ति की बेहतर समझ हो सकती है, साथ ही जटिलताओं का शीघ्र पता लगाया जा सकता है। जिस रोगिष्टता कम हो सकती है।

अध्ययन की समीक्षा किसने की है?

अध्ययन की समीक्षा अनुसंधान आचार समिति द्वारा की गई है।

यदि कोई समस्या हो तो क्या होगा?

यदि आप शिकायत करना चाहते हैं, या इस अध्ययन के दौरान आपसे जिस तरह से संपर्क किया गया या व्यवहार किया गया, उसके किसी भी पहलू के बारे में कोई चिंता है, तो आपको डॉ. □□□□□□ □□□□□ (7990873918 / dp@291198@gmail.com) से संपर्क करना चाहिए।

દર્દીની માહિતી પત્રક:

ભાગ લેવા આમંત્રણ

અમે તમને સર્વેક્ષણ પૂર્ણ કરીને આ સંશોધન અભ્યાસમાં ભાગ લેવા માટે આમંત્રિત કરવા માંગીએ છીએ. તમે ભાગ લેવો કે નહીં તે નક્કી કરો તે પહેલાં, કૃપા કરીને નીચેની માહિતી વાંચવા માટે સમય કાઢો જે સમજાવે છે કે આ સંશોધન શા માટે કરવામાં આવી રહ્યું છે અને તમારી સંડોવણી શું હશે. જો તમે ઈચ્છો તો ટૂથર્સ સાથે વાત કરો અને જો તમને અયોક્કસ હોય તો પ્રશ્નો પૂછવા માટે કૃપા કરીને નિઃસંકોય અનુભવો. ના. આ વાંચવા બદલ આભાર.

અભ્યાસનો હેતુ શું છે?

આ અભ્યાસનો હેતુ ટેમ્પોરલ હાડકાના રોગવિજ્ઞાન માટે એચઆરસીટી ટેમ્પોરલ હાડકાની યોકસાઈનું અન્વેષણ કરવાનો અને એચઆરસીટીના તારણોને ઇન્ટ્રાઓપરેટિવ તારણો સાથે સહસંબંધિત કરવાનો છે. મધ્ય અને આંતરિક કાનની જટિલ રચનાત્મક રચનાને કારણે ટેમ્પોરલ હાડકાનું રેડિયોલોજીકલ મૂલ્યાંકન મુશ્કેલ છે. એચઆરસીટી એલ્ગોરિધમ્સ સ્કેન ટેમ્પોરલ હાડકાની અંદર યોક્કસ સ્થાન અને અબનોરમાલિટીને ઓળખવા માટે એક ઉત્તમ રીઝોલ્યુશન પૂરું પાડે છે અને તેમને ઇન્ટ્રાઓપરેટિવ ઓબ્ઝર્સ સાથે સરખાવી શકાય છે. તે મધ્ય કાનના છુપાયેલા વિસ્તારોને દર્શાવે છે, જેમાં સાઇનસ ટિમ્પેની અને ફેશિયલ રિસેસનો સમાવેશ થાય છે. આનાથી રોગ થવાના કારણો, પેથોલોજી અને રોગના અભ્યાસક્રમની વધુ સારી સમજણ તેમજ ગૂંચવણોની વહેલી શોધ થઇ શકે છે. આનાથી ટેમ્પોરલ હાડકાના જખમ સાથે સંકળાયેલ રોગિષ્ઠતામાં ઘટાડો થશે.

શા માટે મને ભાગ લેવા માટે પસંદ કરવામાં આવ્યો છે?

કારણ કે તમે એવા છો કે જેઓ આ અભ્યાસ માટે મારા સમાવેશના માપદંડોને પૂર્ણ કરે છે.

શું મારે ભાગ લેવો પડશે?

ના, આ અભ્યાસમાં ભાગ લેવો સ્વૈચ્છિક છે. ભાગ લેવો કે નહીં તે નક્કી કરવાનું તમારા પર છે.

હું કેવી રીતે ભાગ લઇ શકું?

માત્ર તેના માટે જાણકાર સંમતિ આપીને.

ગોપનીયતા?

અમે એકત્રિત કરીએ છીએ તે તમામ ડેટા સખત રીતે ગોપનીય રાખવામાં આવશે. સર્વેક્ષણમાં તમે અમને જે માહિતી આપો છો તે એક અનામી ડેટાબેઝમાં દાખલ કરવામાં આવશે જેમાં તમારા વિશે કોઈ વ્યક્તિગત વિગતો હશે નહીં. આ અભ્યાસ એથિક્સ કમિટીના તમામ સંબંધિત માર્ગદર્શનના સંપૂર્ણ પાલનમાં હાથ ધરવામાં આવશે.

ભાગ લેવાની સંભવિત સમસ્યાઓ અને ગેરફાયદા શું છે?

અમે આ અભ્યાસમાં ભાગ લેવાથી ઉદ્ભવતી કોઈપણ સમસ્યાઓની અપેક્ષા કરતા નથી.

ભાગ લેવાના સંભવિત ફાયદા શું છે?

એચઆરસીટી ક્લિનિકલ નિદાનની પુષ્ટિ કરવા અને વધુ સંપૂર્ણ પૂર્વ-ઓપરેટિવ મૂલ્યાંકન પ્રદાન કરવા માટે મદદરૂપ થશે.
આનાથી રોગ થવાના કારણો, પેથોલોજી અને રોગના અભ્યાસક્રમની વધુ સારી સમજણ તેમજ ગૂંચવણોની વહેલી શોધ થઇ શકે છે. આનાથી ટેમ્પોરલ હાડકાના જખમ સાથે સંકળાયેલ રોગિષ્ઠતામાં ઘટાડો થશે.

અભ્યાસની સમીક્ષા કોણે કરી છે?

સંશોધન નીતિશાસ્ત્ર સમિતિ દ્વારા અભ્યાસની સમીક્ષા કરવામાં આવી છે.

જો કોઈ સમસ્યા હોય તો શું?

જો તમે ફરિયાદ કરવા ઈચ્છો છો, અથવા આ અભ્યાસ દરમિયાન તમારી સાથે જે રીતે સંપર્ક કરવામાં આવ્યો છે અથવા સારવાર કરવામાં આવી છે તેના કોઈપણ પાસાઓ વિશે કોઈ ચિંતા હોય, તો તમારે ડૉ. દીમિ પરમાર (7990873918 / dp@291198@gmail.com) નો સંપર્ક કરવો જોઈએ.

CONSENT FORM

(Parul University Institutional Ethics Committee for Human Research)

I '_____'have been explained the research project and also my role in the same in my own language.

I have been explained that the information provided by me shall be kept confidential and will in no way influence my receiving services from hospital. I also understand that I can withdraw from the study at any point time of the interview.

I agree to participate in the above research project voluntarily.

Witness signature: (Signature/Thumb impression)

Name: Date:

Place:

We give one copy information sheet to our client (consent must be in local language)

सहमतिपत्र

(पारुल यूनिवर्सिटी इंस्टीट्यूशनल एथिक्स कमेटी फॉरह्यूमन रिसर्च)

मुझे '_____' को अनुसंधान परियोजना और उसमें मेरी भूमिका के बारे में मेरी अपनी भाषा में समझाया गया है।

मुझे समझाया गया है कि मेरे द्वारा प्रदान की गई जानकारी गोपनीय रखी जाएगी और किसी भी तरह से अस्पताल से मेरी सेवाओं को प्रभावित नहीं करेगी। मैं यह भी समझता हूं कि मैं साक्षात्कार के किसी भी समय अध्ययनसे हट सकता हूं।

मैं उपरोक्त शोध परियोजना में स्वेच्छा से भाग लेने केलिए सहमत हूं।

गवाहकेहस्ताक्षर : (हस्ताक्षर/अंगूठेकानिशान)

नामतारीख :

जगह :

हमअपनेग्राहककोसूचनापत्रकीएकप्रतिदेतेहैं (सहमतिस्थानीयभाषामेंहोनीचाहिए)

સંમતિ ફોર્મ

(પારુલ યુનિવર્સિટી ઇન્સ્ટિટ્યુશનલ એથિક્સ કમિટી ફોર હ્યુમન રિસર્ચ)

મને _____સંશોધન પ્રોજેક્ટ અને તેમાં મારી ભૂમિકા મારી પોતાની ભાષામાં સમજાવવામાં આવી છે.
મને સમજાવવામાં આવ્યું છે કે મારા દ્વારા આપવામાં આવેલી માહિતી ગોપનીય રાખવામાં આવશે અને તે કોઇ પણ રીતે હોસ્પિટલમાંથી મારી સેવાઓને પ્રભાવિત કરશે નહીં. હું એ પણ સમજું છું કે ઇન્ટરવ્યુના કોઈપણ સમયે હું અભ્યાસમાંથી ખસી શકું છું.
હું ઉપરના શોધ પ્રોજેક્ટમાં સ્વૈચ્છિક રીતે સહભાગી છું.

સાક્ષી હસ્તાક્ષર: (સહી/અંગૂઠાની છાપ)

નામ: તારીખ:

સ્થળ:

અમે અમારા ક્લાયન્ટને માહિતી શીટની એક નકલ આપીએ છીએ (સ્થાનિક ભાષામાં સંમતિ હોવી જોઇએ)