Research Title: Evaluation Of Variations Of Optic Nerve Course In Relation To Posterior Paranasal Sinuses In MDCT In A Tertiary Care Center Of Nepal

NCT Number: NCT06077929

Date Of Document: 30th July, 2023

The applicant should confirm that following supporting information are included during application for IRC approval

SN	Documents	Enclosed Yes/No/NA
1.	Covering Letter addressing to the member secretary indicating the submission of the approval of proposal	**Yes**
2.	Protocol (Form A) of the intended study	**Yes**
3.	References- list cited literatures (Minimum 5 References)	**Yes**
4.	Declaration by Principal Investigator- Funding, Conflict of interest, Approval from department/institution	**Yes**
5	Financial Information (Budget)	**Yes**
6.	Sample of Consent Form (In Nepali Language too)	**NA**
7.	Data Collection Instruments/Questionnaires (In Nepali language, if applicable)	**Yes**
8.	Curriculum vitae of principal investigator and Co-PIs	**Yes**
9.	Drugs and devices, including copy of DDA approval for Unregistered drugs	**NA**

NA=Not applicable

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Registration Date:	Registration Number:
Expedited review:	Full house review:
Name of Reviewer 1:	
Name of Reviewer 2:	
Duration of Project:	
Department:	
Approved Date:	

Research Proposal *(Use additional sheet if necessary)*

1. Title of the research: EVALUATION OF VARIATIONS OF OPTIC NERVE COURSE IN RELATION TO POSTERIOR PARANASAL SINUSES IN MDCT IN A TERTIARY CARE CENTER OF NEPAL

2. Introduction: (*300 words*)

A. Background: Optic nerve (ON) originates from eyeball and terminates in the brain. It has intraconal course, extraconal course and intracranial course. Extraconal course of optic nerve shows variations in population. Relationship of optic nerve with posterior paranasal sinus (ethmoid and sphenoid sinuses) are of great clinical importance. Most commonly, ON is supero-lateral to the sphenoid sinus. However, varied protrusion of ON into the posterior paranasal sinuses are seen. Most important of them is onodi cells. If the optic nerve lies just lateral to posterior ethmoid cells, the ethmoid cell is called onodi cell. During endoscopic sinus surgery (ESS), there is high chance of injury to optic nerve if there is optic nerve.

According to DeLano classification, there are four types of optic nerve course. Type -I: optic nerve is supero-lateral to sphenoid sinus, Type 2: ON courses superior to sphenoid sinus with less than 50% indentation in coronal section, Type 3: ON courses superior to sphenoid sinus with more than 50% indentation in coronal section. Type 4: ON is just lateral to ethmoid and sphenoid sinuses (i.e., Onodi cell). While coursing posterior paranasal sinuses, the optic nerves show dehiscence. The optic nerve is encased by dura and thin periosteum. The periosteum might not be present in all cases and while coursing through the sinuses, they are exposed open. These kinds of optic nerves are prone to injury during ESS. Thus, it is imperative to know prevalence of different types of course of optic nerve and dehiscence of optic nerve while coursing through posterior paranasal sinuses.

B. Rationale of Study/ Justification:

The variants of optic nerve course in relation to posterior paranasal sinuses are of clinical importance since some of the variants are prone to injury of optic nerve during functional endoscopic sinus surgery. Prior knowledge of course of optic nerve is of utmost importance

in order to prevent injury of optic nerves. However, there is lack of such kind of study in Nepal. Thus, it is imperative to know true prevalence of different anatomical variants of optic nerve course.

C. Objectives of the study:

General objective: To describe different course of optic nerve in relation to posterior paranasal sinuses and optic nerve dehiscence in MDCT.

Specific objective:

- To obtain the prevalence of different types of course of optic nerves according to DeLano classification in the MDCT of patients visiting our hospital. According to DeLano classification, there are four types of optic nerve course. Type -I: optic nerve is supero-lateral to sphenoid sinus, Type 2: ON courses superior to sphenoid sinus with less than 50% indentation in coronal section, Type 3: ON courses superior to sphenoid sinus with more than 50% indentation in coronal section. Type 4: ON is just lateral to ethmoid and sphenoid sinuses (i.e., Onodi cell).
- To obtain prevalence of optic nerve dehiscence in the MDCT of patients visiting our hospital.
- To obtain prevalence of pneumatized anterior clinoid process in the MDCT of patients visiting our hospital.

3. Literature Review with References (relevant up to five)

In a study by Itagi et al(1), in Indian ethnics, 200 optic nerve canals were assessed and grouped into four types based on the modification of Delano et al. classification. The most common optic nerve course (ONC) was Type-1 (60%), followed by Type-2 (15%), Type-3 (14%) and Type-4 (11%). Dehiscence was seen in 35(17.5%) mostly in Type-3 canals. Pneumatized anterior clinoid process (PACP) was seen in 30 (15%). In another study by BN Ravindra et al(2), in population of

Karnataka, Type 1, Type 2, Type 3, and Type 4 optic nerves was present in 83.33%, 8.87%. 12.1%, and 21.78% respectively. Bilateral Type 1 optic nerves was present in 58.88% patients, both Type 2 and Type 3 optic nerves were seen bilaterally in 3.23% of patients and bilateral Type 4 optic nerve was seen in 10 (8.06%) cases. Optic nerve Type 1 (83.88%) was the most frequent nerve type, followed by Type 4 (21.78%). In another study done by Braggs et al(3) in south Indian population, type 1 had a prevalence of 61.8%, type 2 had a prevalence of 17.8%, type 3 had a prevalence of 7.6%, type 4 had a prevalence of 12.8%. In another study done by Lakhani Mubina et al(4) type 1 ON was found to be the most frequent type; 55.93%, followed by type 2 with a frequency of 26.85%. However, type 3 and type 4 appeared less frequently, that is 11.1% and 6.11%, respectively. When comparing right and left sides it was noted that the frequency of type 1 optic nerve was found to be higher on both right and left sides with a value of 56.30% and 55.5%, respectively. Type 2 showed a frequency of 26.67% on right side and 27% on left side. Type 3 was identified to be 11.4% and 10.7% on right and left sides, respectively. Type 4 optic nerve was found to be the least common type in our study on both sides, i.e., 5.56% on the right side and 6.67% on the left side.

Bibliography

1. Itagi RM, Adiga CP, Kalenahalli K, Goolahally L, Gyanchandani M. Optic Nerve Canal Relation to Posterior Paranasal Sinuses in Indian Ethnics: Review and Objective Classification. J Clin Diagn Res JCDR. 2017 Apr;11(4):TC01–3.

2. Bn R, C D. Evaluation of optic nerve variations in relation to posterior paranasal sinuses among study population of Mandya District of Karnataka State. Int J Radiol Diagn Imaging. 2020 Jul 1;3(3):16–20.

3. Braggs A, S KK. CT Study of Relationship of Optic Nerve to Posterior Paranasal Sinuses. Int J Contemp Med Surg Radiol [Internet]. 2018 Dec [cited 2023 Jun 27];3(4). Available from: https://www.ijcmsr.com/uploads/1/0/2/7/102704056/ijcmsr_161.pdf

4. Mubina Lakhani, Muhammad Ali, Madeeha Sadiq. Analysis of Optic Nerve Types in Relation to Posterior Paranasal Sinuses: A Computed Tomographic (CT) Study. Ann ABBASI SHAHEED Hosp KARACHI Med Dent Coll. 2017 Dec 31;22(4):249–54.

4. Research Methodology:

A. Study type: Quantitative Study
B. Study design: Retrospective Cross Sectional Observational Descriptive Study
C. Sample size: Minimum 319 patient's CT scan; The size was calculated by the following formula for sample size:

   n= Z^2 P (1-P)/ d^2 , Where:

   Z- 2.576 (for 99 percent confidence interval)

   P- Prevalence of most common anatomical variant from previous study (60 %)

   d- margin of error (5%).

   Calculation: (2.576 x 2.576 x 0.6 x 0.4) / (0.05 x 0.05) = 637 optic nerve canals (Since 1 patient has 2 optic nerve canals, number of CT to be studied =319)
D. Inclusion and Exclusion Criteria: All MDCT scan of PNS referred for evaluation of chronic rhinosinusitis and nasal polyposis and Head referred for evaluation of headache, dizziness, loss of consciousness in patients >13 years age are included in the study. MDCT PNS and head done for evaluation of trauma and tumors are excluded from the study.
E. Data collection methods/tools: Images will be studied and findings will be recorded in predesigned Proforma. The proforma is attached herewith.
F. Data analysis methods/tools: Prevalence of the variations of optic nerve course was calculated by using previous study in Indian population and free software like epi info.

5. Work plan/GANTT chart (start, progression, completion time for study/research) and Budgeting.

SN	Tasks	From	To	August	September	October	November
1	Extraction of data	1 August	31 August		[redacted]		
2	Study of data and categorization	1 September	30 September	[redacted]		[redacted]	
3	Data analysis and obtaining result	1 October	31 October	[redacted]			[redacted]
4	Preparing Manuscript	1 November	30 November	[redacted]			

Total duration of study will be of 4 months after the approval.

Funds will be generated from the involved investigators.

First month- Extraction of data from August 1 to August 31 2023
Second month- Study of the data collected and categorized accordingly.
Third month- Data analysis and obtaining the results
Fourth month- Preparing Manuscript.

BUDGET

ITEMS	**Unit**	**Price per unit**	**APPROXIMATE COST**
Stationary			Rs. 1000

Statistician			Rs. 5000
Miscellaneous			Rs. 5000
TOTAL			Rs. 11000

Declaration ***(Please tick)***

S.no	Title	**Yes**	**No**
1.	Are foreign researcher / institutions involved in the research?		**No**
2.	Is your research being funded by organization or agency?		**No**
3.	Are vulnerable members of the population required for this research? (Except routine work treatment/observation in hospital set up e.g., pediatric, obstetric patient, patient in psychiatric hospital, etc.)		**No**
4.	Are there significant risks involved for the participants?		**No**

If any of the declaration is "yes" then please fill up the form "B" with supplemental detail information.

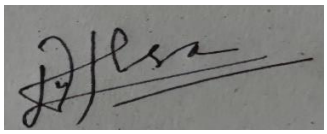
Declaration by the principal investigator

I hereby certify that the above-mentioned statements are true. I have read and understood the regulation of the Nepal Health Research Council (NHRC) and will act accordingly.

If the research is terminated, for any reason, I will notify IRC-GIH of this decision and provide the reasons for such actions. I will provide a written notice upon the completion of the research

as well as a final summary/full report of the research study. For publication in a journal, I shall acknowledge the IRC-GIH approval and shall provide the committee copy of such publication.

Full name (*first/middle/last*): Dr Prajwal Dahal

(Signature) 

Date: 10/07/2023

Email: meprajwal7@gmail.com

Contact No: *(preferably mobile no) : 9841948177*

Data Collecting Instrument of the study 'EVALUATION OF VARIATIONS OF OPTIC NERVE COURSE IN RELATION TO POSTERIOR PARANASAL SINUSES IN MDCT IN A TERTIARY CARE CENTER OF NEPAL'

Name: Age:

Sex: Date:

1)Course of optic nerve: Right: Left:

2)Wall dehiscence of ON: Right side (Present, absent); Left side (Present, absent)

3)Pneumatization of anterior clinoid process: Right side (Present, absent); Left side (Present, absent)