KATHMANDU UNIVERSITY
SCHOOL OF MEDICAL SCIENCES

March 30, 2023

To,

Dr. Ram Bahadur Gurung
Kathmandu University School of Medical Sciences
Dhulikhel, Kavre

Subject: Approval of Research Proposal

Dear Dr. Gurung

This is to certify that the following protocol and related documents have been reviewed and granted approval by Institutional Review Committee, Kathmandu University School of Medical Sciences (IRC, KUSMS) for implementation on 27 March, 2023.

IRC-KUSMS Approval No.	**39/23**	Duration of Approval	26 March, 2024
Principal Investigator	Dr. Ram Bahadur Gurung	Sponsor Institute	N/A
Title	**Clinico-demographic profile of the patient with cholangiocarcinoma undergoing ERCP in Dhulikhel Hospital.**		
Other Members of Research Team (Co- Investigators)	Dr. Prakash Sapkota, Dr. Pasanda Sharma, Shreesuna Katila, Samyog Adhikari.		
IRC-KUSMS, Administrative fee	Rs. 500.00		
Chairperson of IRC-KUSMS	**Name**		
	Prof. Dr. Prabodh Risal		
Investigator Responsibilities: ➢ Comply with all relevant International and NHRC guidelines. ➢ Submit final report after completion of protocol at IRC-KUSMS.			

If you have any questions, please contact the IRC-KUSMS section at Kathmandu University School of Medical Sciences/ Kathmandu University Hospital.

With best regards,

Dr. Dipesh Tamrakar
Member Secretary, IRC-KUSMS

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A. Research Proposal Information

A.1 Title of the study:

Clinico-demographic profile of the patient with cholangiocarcinoma undergoing ERCP in Dhulikhel Hospital.

A.4 List name, affiliation and contact details of all investigator

A4.1 Faculty or Staff or other

Name	Position	Contact address	E-mail address
Dr Ram Bdr. Gurung	Principal Investigator	Dhulikhel Hospital, Endoscopy department	rambgurung7@gmail.com
Dr Pasand Sharma	Co-investigator	Dhulikhel Hospital, Endoscopy department	pasanda@gmail.com
Dr Prakash Sapkota	Co-investigator	Dhulikhel Hospital, Endoscopy department	drprakash@kusms.edu.np

A4.2 Students

Name	Position	Contact address	E-mail address
Shreesuna Katila	Co-investigator	Kathmandu University School of Medical Sciences, Dhulikhel, Nepal	shreesuna95@gmail.com
Samyog Adhikari	Co-investigator	Kathmandu University School of Medical Sciences, Dhulikhel, Nepal	adhikarisamyog90@gmail.com

A.5 Contact detail

Dr Ram Bdr Gurung, Head of the Department, Internal Medicine, Dhulikhel Hospital, Dhulikhel,6, Kavre.
Email address: ramgurung7@gmail.com

A.6 Nature of Study

□ Clinical trial phase…/ Intervention study
□ Bioequivalence/ pharmacokinetic drug study
□ Epidemiological research
□ Laboratory study
□ Social/ behavioral research
□ Study using stored specimens/tissue
☒ Study using stored medical records
□ Others……

A.7 Is study single center or multicenter

☒ Single center
□ Multicenter (within Nepal)
Please specify the study sites …….....
□ Multicenter (International)
Please specify the study sites …….....

Note: NHRC Approval is compulsory for Ph. D/ International Study/ International Collaboration/ Multicenter & Clinical Trial Study.

A.8 Summary of the proposed research protocol (within 200 words)

Cholangiocarcinoma (CCA) or a bile duct cancer is regarded as the second most frequent type of primary liver cancer which is diagnosed in the late decades of life with fatal outcomes. Its risk factors include primary sclerosing cholangitis, hepatitis, smoking, alcohol, obesity, inflammatory bowel disease, cirrhosis, etc. As it is a fatal disease with late diagnosis, knowing the risk factors and its occurrence rate will be helpful to design interventions based on the evidence. It is also important for the early treatment and increased survival rate of patients. It is a quantitative observational type of study. The objective of this study is to collect the clinico-demographic profile of the patients with cholangiocarcinoma undergoing Endoscopic Retrograde Cholangiopancreatography (ERCP) in Dhulikhel Hospital. Self- structured Questionnaire will be used as a research tool for data collection based on literature review. This kind of research is crucial to widen the knowledge in prevention of the morbidity and mortality due to cholangiocarcinoma. Dhulikhel Hospital is a pioneer tertiary care center in Nepal for ERCP, where cases are from different parts of Nepal and their medical records will be reviewed to generate the

evidence of the clinico-demographic profile of the patient with cholangiocarcinoma undergoing ERCP.

A.9 Source of Funding/Sponsor

Non Funded

A.11 Declaration of Co-I

None

B. DETAIL OF THE STUDY

B.1. Background:

Bile is a complex aqueous secretion that originates from hepatocytes of liver then stored and concentrated in gallbladder or is delivered directly to the intestinal lumen whose function is to break down fats and help the body to remove excretory products.[1] Bile duct is a tube which connects gallbladder and liver to the small intestine to allows flow of bile into the small intestine.[1] Cholangiocarcinoma (CCA) is an epithelial cell malignancy of biliary tree that arises from varying locations.[2] Of three types i.e Extra hepatic, Hilar and Intra hepatic cholangiocarcinoma, Extra hepatic is the most common and most treatable form of cholangiocarcinoma.[3–5] Risk factors include primary sclerosing cholangitis, hepatitis, smoking, alcohol, obesity, inflammatory bowel disease, cirrhosis, host genetic polymorphisms,etc.[6]

Discussing the data of cholangiocarcinoma, these are most common in Southeast and East Asia due to the prevalence of parasitic infection in those particular areas as it is one of the important causes of cholangiocarcinoma.[7] *Ophisthorchis Viverrini* and *Clonorchis sinensis* are the hepatobiliary flukes mainly associated with CCA in Southeast Asia.[6]. A study done in the United States stated the continued increment in incidence of cholangiocarcinoma from 2001-2017 with greater increase in intrahepatic CCA than extrahepatic CCA. [8] Different liver flukes are also associated with cholangiocarcinoma in countries like Vietnam, Thailand, Korea, China, Vietnam, etc.[7]

Accounting for about 2% of all malignancies, CCA is considered as a rare malignancy.[9] It rarely occurs before the fourth decade of life with a wide variation of incidence rates in different geographical regions that reflect the distribution of risk factors, both environmental and genetic.[9,10] Hence it is known as the disease with late diagnosis and fatal outcome.[11] This form of cancer is prevalent in males compared to females and it is found to affect people in their fifth to seventh decade of life.[11] According to the American Cancer Society (2023), about 41,420 cases of liver and intra hepatic cancer are estimated including both sexes among which 29,380 deaths is reckoned.[12] CCA is regarded as the second most frequent type of primary liver cancer.[13] Risk factors related to CCA may vary within different geographical variations.[14] In case of hepatobiliary cancers, CCA accounts for about 20% of death whereas it constitutes 13% of total cancer mortality. [15] As it is not more frequently diagnosed worldwide, it is also regarded as an orphan cancer.[16]

The treatment choice of CCA either surgical or radiological, is dependent on different factors such as anatomical position, lymph node and vascular invasion, metastatic condition, etc**.** [13,16] In case of chemotherapy, combination of gemcitabine and cisplatin has been considered as a standard chemotherapy regimen as the combination of both of them has been shown overall survival rate of 3.6 months as compared to gemcitabine alone.[17] Patients are usually diagnosed at older age and further it is made worse by symptoms such as pruritus, jaundice, ascites, etc.[18] There has been limited information on the application of autoantibodies (AABs) as biomarkers in case of primary liver tumors such as CCA so far.[19] However, carbohydrate antigen 19-9 (CA19-9) and carcinoembryonic antigen (CEA) were the most commonly studied biomarkers.[19]

B.2. Statement of the problem/ rationale/ need of the study:

Studies have shown that the death rate from Cancer is increasing globally, especially in low and middle income countries.[19,20] Incidence of CCA is increasing in western countries during the last decades and increasing tremendously in Asian countries as well. [10,19,20] The number of CCA raised from 1720 in 2010 to 2161 in 2013 in England.[21] The highest incidence of CCA has been reported in northeast Thailand.[22]

Nepal being an Asian country is also in the region to have increased cases of cholangiocarcinoma and need rigorous scientific studies to generate evidence to prepare interventions on its prevention and treatment. Cholangiocarcinoma being the major contributing factor for the death of the humans, this needs early diagnosis and treatment system to intrude the increasing mortality and morbidities. Studies should be conducted in its risk factors, disease status, occurrence and other factors so that such studies are considered to estimate the prevention and management of such deadly diseases.

The studies on this sector is in dearth and is in great need of the involvement of academia, medical centers and different institutions. Such studies will provide evidence to plan several interventions for its better and efficient prevention and treatment option.

B.3. Research hypothesis (if applicable):

NA

B.4. Objectives of the research:

General objective (s)

The aim of the study is to assess the clinico-demographic profile of the patient with cholangio-carcinoma undergoing ERCP in Dhulikhel Hospital.

Specific objective(s):

This study holds the objective,

- To identify clinical profile of the patient with cholangio-carcinoma undergoing ERCP
- To describe the demographic profile of the patient with cholangio-carcinoma undergoing ERCP
- To measure the outcome of ERCP procedure in them.
- To identify the association between demographic variable and clinical presentation of the patient with cholangio-carcinoma undergoing ERCP

B.5. Study site and justification:

The study will be conducted in the Endoscopy unit of the Internal medicine department of Dhulikhel Hospital. This hospital has provided services to more than 50 out of 75 districts of the country. It provides services to about 2.7 million people from Kavrepalanchowk, Sindhupalchowk, Dolakha, Lalitpur, Kathmandu, Sindhuli, Ramechhap and other surrounding districts per-year. In Nepal ERCP procedure has been limited to very few Tertiary centers and Dhulikhel Hospital is the pioneer institute to provide the ERCP procedure (since 2011) in the nation. This procedure is mainly performed for the indication of choledocolithiasis, obstructive Jaundice, acute biliary pancreatitis, cholangiocarcinoma, etc. In 2019 only, a total of 1352 patients had undergone ERCP in Dhulikhel Hospital as per the monthly ERCP report book obtained from the Department of Endoscopy of Dhulikhel Hospital.

B6. METHODS/ METHODOLOGY:

***B.6.1 Research* Methods** *(Cross in the appropriate box)*

a) Qualitative Research ☐ *Quantitative Research* ☒ *c) Mixed Research* ☐

B.6.2. Study design:

This is a quantitative, retrospective, descriptive cross-sectional observational study.. The outcome and the exposure will be measured at the same time as a snapshot.

B.6.3. Study Variables

The study variables will be the socio-demographic variables and the clinical details of the study participants.

B.6.4. Expected outcomes of the research

The expected outcome of the research is to present a clinical finding of this under studied clinical area in Nepal. Furthermore, this will be a reference for the future researchers to conduct further studies on this sector to enhance the prevention, management and the treatment services.

B.7 STUDY POPULATION AND SAMPLE

B.7.1. Participants/ study population:

Patients with cholangiocarcinoma who had undergone ERCP in Endoscopic Department of Dhulikhel Hospital. The patient's information will be obtained from patients' medical records from the outpatient and inpatient department of Dhulikhel Hospital. Thus, the person will not be contacted directly for the data collection.

B.7.2 Selection criteria:

Inclusion criteria:

- All the participants with cholangiocarcinoma had undergone ERCP
- above 18 years of age.

Exclusion criteria:

- ERCP failed cases

B.7.3. Sampling method/ technique:

We will do purposive sampling from the eligible list obtained from the medical records.

B.7.4. Sampling Unit:

The sampling unit is the patient with cholangiocarcinoma who had undergone ERCP.

B.7.5 Sample size determination:

All the eligible cases listed in the medical record of Dhulikhel Hospital from January 2017 to January 2023. Hospital records showed approximately 75 cases of cholangiocarcinoma per year. So, we will conduct a total population sampling with an estimated sample size of 375.

B.8. Procedure:

First of all, the researcher will get formal approval for data collection in the institution.

- After ethical clearance, data will be collected through a case sheet of the patient and record of ERCP procedure at the department using prepared Per forma.
- Data of procedure outcome will be collected via call to the patient. Before collecting information from the respondent, they will be informed about the objective of the study and will be assured of privacy and volunteering participation.

B.8.1. Data Collection Tools/ Measures:

- Clinical Proforma will be used to collect data

Part I: Socio-Demographic information of patient

Part II: Information related to Clinical profile of patient

Part III: outcome of ERCP procedure

- The data will then be entered into Microsoft Excel for further data management.

B.8.2. Pretesting

The proforma will be pretested entering about 10 cases so that we can further modify the proforma.

B.8.3. Validity and Reliability of tool

The tool will be the proforma and this will be based on other literatures and as per the experts suggestion. Indeed, the principal investigator is the physician (expert) to perform this procedure in Nepal and other team members have some kind of exposure in this sector.

B.9. Plan for specimen/data management:

(a) Data Processing

- Collected data will be stored in a file to prevent loss or damage.
- Data will be coded and entered in Microsoft Excel Sheet and will be transferred to the Statistical Program for Social Science (SPSS) for further analysis.

(b) Presentation of Data

- Data will be categorized on the basis of research objectives.
- The study will present the descriptive statistics and other details of the variables.

B.10. Plan for data analysis:

B.10. a. SPSS (Statistical Program for Social Science) version 25.0 will be used for descriptive as well as inferential statistics.
B.10. b. Statistical tests: Descriptive statistics (mean, frequency, standard deviation and percentage) will be applied. For inferential statistics, Chi-square test will be used for the analysis of the categorical data while, t-test or correlation will be done for the continuous variables.

B.11. Potential Biases:
There may be some confounders that will direct to the bias of the study. The information in the confounders will be collected and if required will be adjusted in the data analysis.

B.12. Limitations of the study:
- This is not a common disease, so the sample size of the eligible participants is limited.
- The retrospective study nature of this study may not allow us to incorporate as much information as we are seeking. However, future research may address these issues.

B.13. Plan for supervision and monitoring:
- Data will be collected by the co-authors
- Supervision and monitoring will be done by Principal Investigator and the research team

B.14. Plan for dissemination of the research:
The research will be disseminated to:
- Conferences
- Publication in one of the index peer review journal

B.15. **DATA AND SPECIMEN BANKING AND/OR SHARING**

B15.1 Management of specimen/data archiving or left-over

NA

B15.2 Specimen/data sharing plan

NA

C. ETHICAL CONSIDERATION

10.1. Ethical issues	Yes/ No	Justification if yes
a. Are human participants included in the study?	**Yes**	The study aims to determine the clinico-demographic profile of the patients with cholangiocarcinoma undergoing ERCP in Dhulikhel Hospital. But we will not have face to face interaction, as all the information will be obtained from the medical records.
b. Are **vulnerable members** of the population required for this research? *(includes age under 18, pregnant women etc)*	No	
c. Are there any risks involved for the participants? If yes, identify clearly what are the expected risks for the human participants in the research and provide a justification for these risks.	No	
d. Are there any benefits involved for the participants? If yes, identify clearly what are the expected benefits for the participants.	No	

C1. SIGNIFICANCE OF THE STUDY

- The study can reveal some risk factors associated with the particular disease i.e Cholangiocarcinoma. Thus, it can be regarded as a baseline study for conducting any intervention.
- It can also be used as a reference for future study purposes in similar types of study.

C2. BALANCE OF RISK AND BENEFIT

C2.1 Risk of the study and Preventive and alleviative measures for risk

C2.1. Risk management:	
Potential risks identified	**Proposed measures to mitigate risks**
1. No direct risk/harm to the study participants as medical records will be reviewed primarily for patient data collection.	NA
2. Information on the patient's current status will be gathered via telephone interview (only for the feasible cases) where they may have to spare a few minutes for the data, however, this will take only a few minutes.	Verbal consent will be taken and all the information will be provided to the participants if the interaction is required.

C2.3 Benefits of the study

The study will be helpful to the future researcher to base on this and plan further studies so that we can enhance the prevention and treatment processes.

C3. CONSIDERATION FOR VULNERABLE RESEARCH PARTICIPANTS

Check whether your study involves any of the following vulnerable research participants.

- ☐ Prisoners
- ☐ Pregnant women
- ☐ Mentally ill persons
- ☒ Cancer or terminally ill patients
- ☐ Neonates/infants/children (aged <18)
- ☐ HIV/AIDS patients
- ☐ Institutionalized persons e.g. military, students, etc.
- □ Others (please specify)……..….

The study participants are cancer patients, but we will not directly interact with them, this study will only review the medical records from the past years.

C4. <u>OBTAINING THE CONSENT:</u>

It is a retrospective study, while collecting information by making a call to the participants, verbal consent will be obtained.

C4. a. How will the informed consent be obtained from the research participants?

Only verbal consent will be taken by phone and that will be to follow up the few things that will ensure the status of the patients.

C4.b. Who will obtain the consent from the study participants?

- Co-authors will obtain verbal consent on the telephone.

C4. c. Is there anything being withheld from the research participants at the time the informed consent is being sought? Mention "YES" or "NO

NO

C4.d Compensation for research participants

☐ Yes, please provide details:

……..……

☒ No, please provide reasons: This is a retrospective study and the data will be obtained from medical records and ERCP procedure of the patients.

D. APPENDIX
D.1 REFERENCES

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D.2.Consent form:

Title of the study: Clinico-demographic profile of the patient with Cholangiocarcinoma undergoing ERCP in Dhulikhel Hospital

Introduction and consent:
I am Doctor Ram Bahadur Gurung, Associate professor of Kathmandu University School of Medical Sciences, Dhulikhel Hospital. I am conducting research on "**Clinico Demographic profile of the patient with cholangiocarcinoma undergoing ERCP in Dhulikhel Hospital "**. I ascertain you that the information you provide will be confidential and used for the study purpose only. Participation in this study is completely voluntary. You may withdraw at any time from this study without giving any reason. Any queries, misunderstanding can be dealt with by the researcher.
If you are willing to be a participant of this research, please put a tick below:
I agree ☐ I disagree ☐

Date of collection:
Name of researcher:
Sign of researcher:
Date:
Serial no.:

Direction: Please give the correct answer to the questions. I ensure that the information given would be used for study purposes only and will be kept confidential. I will be thankful for your kind cooperation.

Address……

English Questionnaire

PART 1: SOCIO-DEMOGRAPHIC CHARACTERISTICS

1. **Age** (in completed years)……..

2. **Gender:**

   ☐ Male ☐ Female Others (specify).....

3. **Ethnicity**
   a. Brahimin/chhetri
   b. Newar
   c. Mongolian
   d. Dalit
   e. Terai region
   f.

4. **Occupation**
   a. Agriculture
   b. Service
   c. Labor
   d. House maker
   e. Student

5. **Food habit**
   a. Vegetarian
   b. Non-Vegetarian

6. **Smoking Habit**
   a. Yes
   b. No

7. **Alcohol Intake**
   a. Non-alcoholic
   b. Moderate
   c. Significant

Part 2: Information related to Clinical profile of the patient

1. **Mode of presentation**
   a. Cholangitis
   b. Obstructive Jaundice
   c. Non-icteric Cholestasis

2. **Comorbidity**
   a. Yes
   b. No

3. **Symptoms**
   a. Itching
   b. Abdominal Pain
   c. Asymptomatic Jaundice
   d. Anorexia
   e. Weight loss

4. **Investigations**
   a. USG
   b. CT Scan
   c. MRI
   d. MRCP
   e. EUS

5. **EUS FNA**

   a) Yes b)No

6. **If Yes**
   1) Positive
   2) Negative

7. **Brush cytology**

   a) Yes b) No

8. **If Yes**
   1) Positive
   2) Negative

9. **Intra ductal biopsy**

a) Yes b) No

10. If Yes

1) Positive
2) Negative

11. **Surgical operability**

a. Operable
b. Non-operable
c. Unknown

12. Lab reports

a) Total bilirubin……
b) Direct bilirubin…….
c) ALP……
d) GGT……
e) AST……
f) ALT……
g) PT……..
h) INR……

13. Type of growth

a. Distal
b. Hilar
    1) Bismuth-I
    2) Bismuth-II
    3) Bismuth-III
    4) Bismuth-IV
    5) Bismuth-V

Part 3. Outcome of ERCP procedure

14. Type of stent used in ERCP:

a) Plastic stent
b) Metal stent (SEMS)

15. Outcome of Stenting

a) Immediate
b) Failed Stenting
c) Successful stenting

16. Complications

a) Perforation
b) Bleeding
c) PEP
d) PEC

17. If PEP done

1) Within 2 weeks
2) After 2 weeks

18. If PEC done

1) Within 2 weeks
2) After 2 weeks

19. Restenting

a) Yes
   1) Within 1 month
   2) Within 2 month
   3) Within 3 month

b) No

20. Radio- Frequency Ablation

- Yes
- No

21. Survival Rate

a) < 1 month
b) 3-6 month
c) 6 month- 1 year
d) >1 year