DONGOLA UNIVERSITY

FACULTY OF MEDICINE

DEPARTMENT OF COMMUNITY MEDICINE

RESEARCH PROPOSAL

Clinical Characteristics and Treatment Patterns of Breast Cancer Patients at Merowe Oncology Center, Northern Sudan2026

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1. Introduction

1.1 Background

Breast cancer is the most commonly diagnosed cancer among women worldwide. In 2024, an estimated 2.43 million new cases and approximately 693,660 deaths occurred globally, making it the leading cancer among women in incidence worldwide and in 164 countries [1].

The burden is disproportionately high in lower-HDI settings, where differences in early detection, diagnosis, treatment access, and health-system capacity contribute to higher mortality [1,2]. In sub-Saharan Africa, late-stage presentation remains common. A systematic review and meta-analysis reported substantial variation in stage at diagnosis, with most patients presenting with stage III or IV disease [3]. More recent evidence from 125 studies involving 42,689 patients found that 63.1% were diagnosed with stage III or IV disease [4].

In Sudan, breast cancer is the leading cancer among women. GLOBOCAN 2022 estimated 6,631 new cases, representing 38.4% of all cancers diagnosed among females [5]. A national spatial-distribution study also identified Northern State among areas with a high estimated breast cancer burden [6]. Sudanese studies have demonstrated advanced-stage presentation and delays in care. A multicenter study of 601 women found that 50.1% had locally advanced or metastatic disease, with a median interval of 221 days from symptom onset to initiation of oncological treatment [7]. Another study reported that 58.4% of women delayed seeking medical advice for more than three months after noticing symptoms [8]. In addition, incomplete diagnostic work-up, including missing staging and/or receptor-status information, was reported in 49% of breast cancer records at the Radiation and Isotope Center Khartoum [9].

Merowe Oncology Center provides oncology services to patients from Merowe, surrounding areas, and potentially other parts of Sudan through referral. However, published evidence describing the clinical characteristics and treatment patterns of breast cancer patients managed at the center is limited. Therefore, reviewing available medical records can provide important center-specific evidence.

1.2 Problem Statement

Breast cancer remains a major public health problem, particularly in low- and middle-income countries, where delayed diagnosis and limited access to comprehensive

treatment contribute to poorer outcomes [1]. In Sudan, it accounted for 38.4% of all newly diagnosed cancers among females in 2022, making it the country's leading cancer among women [5].

Evidence from Sudan indicates frequent advanced-stage presentation and delays in treatment. A multicenter study reported locally advanced or metastatic disease in 50.1% of 601 women, with a median 221-day interval from symptom onset to treatment [7]. Similarly, a study at the National Cancer Institute–University of Gezira reported stage III disease in 48.0% and stage IV disease in 17.3% of patients, with advanced stage and lymph-node involvement associated with poorer survival [10]. A seven-year retrospective study at the East Oncology Centre in Gadarif involving 394 patients further demonstrated the importance of documenting local demographic, clinical, pathological, and treatment patterns [11].

Documentation is another concern. At the Radiation and Isotopes Center Khartoum, 49% of breast cancer records had incomplete diagnostic work-up, including missing staging and/or receptor-status information [9].

1.3 Justification

Breast cancer represents a substantial burden in Sudan, with 6,631 new cases estimated in 2022 [5]. Evidence of advanced-stage presentation and delays in treatment further highlights the need for center-specific assessment [10].

Previous Sudanese studies have mainly focused on oncology centers in Khartoum, Gezira, and Eastern Sudan [10,11]. Their findings may not fully represent patients managed at Merowe Oncology Center because population characteristics, referral pathways, geographical accessibility, diagnostic resources, and treatment availability may differ between settings.

Furthermore, documented deficiencies in diagnostic and treatment records emphasize the importance of assessing the completeness of clinically relevant information in routine oncology practice [9]. This study will therefore describe the demographic and clinical characteristics, disease stage, histopathological findings, hormone-receptor and HER2 status where available, and treatment modalities of breast cancer patients managed at Dongola/ Merowe Oncology Center..

1.4 General Objective

To assess the clinical characteristics, disease stage, treatment patterns, and medical-record documentation of breast cancer patients who attended or were registered at Merowe Oncology Center, Northern State, Sudan, from January 2023 to September 2026.

1.5 Specific Objectives

1. To describe the demographic characteristics of breast cancer patients attending or registered at Merowe Oncology Center, including age, sex, residence, and marital status.

2. To describe the clinical and pathological characteristics of breast cancer patients, including presenting symptoms, tumor size, lymph-node status, clinical stage, histological type and grade, ER, PR, and HER2 status, where documented.

3. To describe the treatment patterns documented among breast cancer patients, including surgery, chemotherapy, radiotherapy, hormonal therapy, and targeted therapy.

4. To determine the proportion of patients presenting with advanced-stage breast cancer (stage III or IV) and assess its association with selected demographic, clinical, and pathological characteristics, where sufficient data are available.

5. To assess the completeness of medical-record documentation of key demographic, diagnostic, pathological, staging, and treatment-related information.

Research Questions

- What are the clinical characteristics and treatment patterns of breast cancer patients who attended or were registered at Merowe Oncology Center, Northern Sudan, from January 2023 to September 2026?
- What proportion of patients presented with advanced-stage breast cancer, and what demographic, clinical, and pathological characteristics are associated with advanced stage?
- How complete are the available medical records with respect to diagnosis, staging, receptor status, and treatment documentation?

2. Literature Review

2.1 Global and African Burden

Female breast cancer is the most commonly diagnosed cancer among women worldwide, with approximately 2.43 million new cases and 693,660 deaths estimated in 2024. Global disparities in outcomes are strongly influenced by socioeconomic development and access to timely diagnosis, staging, pathology, and comprehensive treatment [1,2].

In sub-Saharan Africa, late-stage presentation remains a major challenge. A

systematic review of 83 studies involving 26,788 women found substantial variation in stage at diagnosis, with many patients presenting with stage III or IV disease [3]. An updated review of 125 studies involving 42,689 patients reported that 63.1% had stage III or IV disease and demonstrated regional variation in molecular subtypes [4].

2.2 Clinicopathological Characteristics and Breast Cancer in Sudan

Important clinicopathological characteristics include age, tumor size, lymph-node involvement, histological type and grade, clinical stage, and ER, PR, and HER2 status, which are important for classification and treatment planning [12]. Research involving Sudanese and Eritrean women demonstrated variation in immunohistochemically defined breast cancer subtypes [12], while another Sudanese study reported younger age, larger tumors, higher grade and stage, and greater lymph-node involvement compared with a Northern Italian population [13].

Breast cancer is the leading cancer among Sudanese women, with 6,631 new cases estimated in 2022, representing 38.4% of all female cancers [5]. Northern State was among areas with a high estimated burden in a national spatial-distribution study [6].

2.3 Presentation, Treatment, and Documentation in Sudan

A multicenter study of 601 Sudanese women found locally advanced or metastatic disease in 50.1% and a median 221-day interval from symptom onset to treatment [7]. Another study reported that 58.4% of 149 women delayed seeking medical advice for more than three months [8]. Studies at the National Cancer Institute–University of Gezira and East Oncology Centre in Gadarif documented advanced-stage disease and varied treatment patterns [10,11].

Incomplete diagnostic documentation is also reported; 49% of records at the Radiation and Isotope Center Khartoum had incomplete work-up, including missing receptor status and/or staging [9].

2.4 Research Gap

Despite studies from several Sudanese regions, published evidence specifically describing breast cancer patients managed at Merowe Oncology Center remains limited. This study will review records from January 2023 to September 2026, including patients initially diagnosed at other healthcare facilities, to describe local clinicopathological characteristics and treatment patterns.

3. Materials and Methods

3.1 Study Design

A retrospective study based on review of medical records.

3.2 Study Area

The study will be conducted at Merowe Oncology Center, Northern State, Sudan.

3.3 Study Period

The study will be conducted from September 2026 to November 2026. Medical records of eligible breast cancer patients who attended or were registered at Merowe Oncology Center from January 2023 to September 2026 will be reviewed.

3.4 Study Population

The study population will include all patients with a documented diagnosis of breast cancer who attended or were registered at Merowe Oncology Center between January 2023 and September 2026. The diagnosis may have been established at Merowe Oncology Center or at another healthcare facility. Patients referred to Merowe Oncology Center during the study period for treatment, follow-up, consultation, or other oncology services will be eligible.

3.5 Sampling and Sample Size

A total (census) sampling technique will be used. All eligible breast cancer records available at Merowe Oncology Center for the period January 2023 to September 2026 will be included. Therefore, no probability-based sample-size calculation will be required. The final sample size will be the total number of unique eligible breast cancer patient records identified during the specified period.

3.6 Inclusion Criteria

- Patients with a documented diagnosis of breast cancer who attended or were registered at Merowe Oncology Center between January 2023 and September 2026.
- Patients whose breast cancer diagnosis was established at Merowe Oncology Center or at another healthcare facility.
- Patients referred to Merowe Oncology Center for treatment, follow-up, consultation, or other oncology services during the specified period.

3.7 Exclusion Criteria

- Duplicate records belonging to the same patient.
- Records with insufficient information to establish that the patient attended or was registered at Merowe Oncology Center during the study period.

3.8 Methods of Data Collection

A pre-designed data-collection sheet will be used to extract information from paper

and/or electronic medical records. Where available, information obtained from referral documents, pathology reports, imaging reports, treatment records, and other records maintained at the center will be included.

Demographic data: age, sex, marital status, residence.

Clinical data: presenting symptoms, duration of symptoms, tumor size, lymph-node status, metastatic disease, and clinical stage.

Pathological data: histological type, histological grade, ER, PR, and HER2 status.

Treatment data: surgery, chemotherapy, radiotherapy, hormonal therapy, targeted therapy, and treatment completion/documentation status.

Diagnostic-source data: whether the initial diagnosis was established at Merowe Oncology Center or at another healthcare facility, where documented.

3.9 Study Variables

Dependent variables: treatment modalities received/documented and advanced-stage presentation (stage III/IV), according to the relevant analysis.

Independent variables: age, sex, residence, marital status, family history, presenting symptoms, symptom duration, tumor size, lymph-node involvement, clinical stage, histological type, tumor grade, ER/PR/HER2 status, menopausal status, and source of initial diagnosis, where documented.

3.10.Operational Definitions

Breast Cancer: Histologically or clinically documented malignant breast neoplasm.

Breast Cancer Patient: A patient with documented breast cancer who attended or was registered at Merowe Oncology Center during the study period.

Advanced Stage: Stage III or IV breast cancer as documented in the medical record.

Early Stage: Stage I or II breast cancer as documented in the medical record.

Histopathological Characteristics: Documented histological type and tumor grade.

Receptor Status: Documented ER, PR, and HER2 status.

Treatment Modalities: Documented surgery, chemotherapy, radiotherapy, hormonal, or targeted therapy.

Incomplete Record: Missing one or more relevant clinical, pathological, staging, receptor, or treatment variables.

Study Period: January 2023 to September 2026.

3.11. Data Management

- Data entry with double-checking of entered information.

- Coding of variables before analysis.
- Data cleaning, including checking missing values, duplicates, and outliers.
- Use of a password-protected database.
- Removal of direct personal identifiers from the research database and use of coded study numbers.

3.12. Data Analysis

Data will be entered, cleaned, coded, and analyzed using IBM SPSS Statistics. Continuous variables will be summarized using mean ± standard deviation or median and interquartile range, as appropriate, while categorical variables will be presented as frequencies and percentages. Disease stage, pathological characteristics, receptor status, and treatment modalities will be described, with the proportion of advanced-stage disease calculated among patients with documented staging. Associations between categorical variables and advanced-stage disease will be assessed using Chi-square or Fisher's exact test. Where appropriate, binary logistic regression will be used to explore factors associated with advanced-stage disease, reporting adjusted odds ratios with 95% confidence intervals. Missing data will be documented for key variables and analyzed using available data without automatically excluding eligible patients.

3.13. Ethical Clearance

Ethical approval will be obtained from the ministry of health Northern State, ethics committee, and administrative permission will be obtained from Merowe Oncology Center. Patient confidentiality will be maintained. Names, national identification numbers, telephone numbers, and other direct identifiers will not be entered into the research database. Data will be used strictly for research purposes.

4. Time-line

Phase	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11
Proposal finalization and ethical/administrative approval	■	■									
Pilot testing of data-collection sheet			■								
Data collection from medical records				■	■	■	■				
Data entry and cleaning								■			
Statistical analysis									■		
Report writing, review, and final submission										■	■

5. Budget Breakdown

Item	Estimated Cost
Printing of data-collection sheets	40,000
Data collector fees (2 collectors × 4 weeks)	56,000
Local transportation	80,000
Statistician / data analysis support	200,000
Stationery and office supplies	50,000
Communication (phone/internet)	20,000
Printing and binding of final report	50,000
Contingency	40,000
Total Estimated Budget	**536,000**

Note: Budget figures are provisional and should be revised according to actual local prices and the requirements of the funding institution.

7. References

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