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Research Proposal

# Association between Perinatal Factors and Simple Febrile Seizures among Children Aged 6–60 Months at Dongola Hospitals, 2026

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## 1. Introduction

### 1.1 Background

A febrile seizure (FS) is defined as a seizure occurring in a child aged 6 to 60 months, accompanied by a body temperature of 38°C or higher, that is not caused by central nervous system infection, an acute metabolic disturbance, and does not occur in a child with a prior history of afebrile seizures. FS are the most common convulsive disorder of early childhood, affecting an estimated 2–5% of children in Western populations, with higher figures of up to 8–10% reported from some Asian and African settings. FS are classified as simple (generalized, lasting less than 15 minutes, and not recurring within 24 hours) or complex (focal, prolonged, or recurrent within the same febrile illness).(1)

The pathogenesis of FS is multifactorial, resulting from an interaction between genetic susceptibility, brain maturation, and environmental precipitants such as the rate and height of temperature rise. Beyond genetic and familial predisposition, a growing body of evidence links the antenatal and perinatal period to later susceptibility to FS. Factors such as mode of delivery, gestational age at birth, birth weight, birth asphyxia and low Apgar scores, neonatal jaundice, admission to the neonatal intensive care unit, maternal illness during pregnancy, and duration of breastfeeding have all been investigated as possible perinatal antecedents of FS (2-3).

Although SFS generally carry an excellent prognosis, they remain a frequent and frightening presentation to paediatric emergency and outpatient departments, and a source of considerable parental anxiety. Understanding which perinatal exposures are associated with an increased risk of SFS in a given population can help clinicians identify children who may benefit from closer follow-up, targeted parental counselling, and can highlight opportunities for improving the quality of antenatal and perinatal care.

### 1.2 Problem Statement

Simple febrile seizures SFS are among the commonest reasons for pediatric consultation at Dongola Hospitals, yet the perinatal risk profile of affected children in this locality has not been systematically documented. Most of the available evidence on perinatal antecedents of FS originates from Asian, Middle Eastern, European and, to a lesser extent, sub-Saharan African populations, whose obstetric practices, nutritional status, and health-service utilization differ considerably from those of Northern State, Sudan. In the absence of locally generated evidence, clinicians at Dongola Hospitals currently have no objective basis on which to identify children who are at particularly high risk of FS on account of their perinatal history, and opportunities for early counselling of at-risk families may consequently be missed.

### 1.3 Justification

SFS are the most common seizure type in early childhood, and perinatal exposures such as prematurity,

low birth weight, mode of delivery, and feeding practices have been linked to their occurrence. However, most of this evidence comes from Western, Asian, and Middle Eastern populations whose obstetric and health-service contexts differ from those of Northern State, Sudan . To our knowledge, no published Sudanese study has examined this association(5).

An analytic cross-sectional design is appropriate for this question. It allows the prevalence of each perinatal factor to be compared between children with SFS and febrile children without seizures, and the strength of association to be estimated using odds ratios with 95% confidence intervals, at a single point in time and at relatively low cost(7).

### 1.4 Research Question:

Is there an association between perinatal factors and simple febrile seizures among children aged 6–60 months in Dongola hospitals in 2026?

### 1.5 Study Hypothesis

**1. Null Hypothesis ($H_0$):**

There is no significant association between perinatal factors and SFS among children aged 6–60 months in Dongola hospitals in 2026.

**2. Alternative Hypothesis ($H_1$):**

There is a significant association between perinatal factors and SFS among children aged 6–60 months in Dongola hospitals in 2026.

### 1.6 Research Objectives

**General Objective:**

To describe the perinatal factors among children aged 6–60 months presenting with SFS at Dongola Hospitals, 2026.

**Specific Objectives:**

1. To describe the socio-demographic characteristics of children presenting with SFS.

2. To determine the frequency of selected perinatal factors, including mode of delivery, gestational age, birth weight, birth asphyxia, Apgar score, neonatal jaundice, NICU admission, and maternal illness during pregnancy.

3. To describe the antenatal, delivery, neonatal, and feeding histories of children with SFS.

4. To describe the clinical characteristics of SFS among the study participants, including age at presentation, sex, fever characteristics, seizure duration, and recurrence within the current febrile illness.

## 2. Literature Review

### 2.1 International Studies

In one of the earliest large-scale analyses, Nelson and Ellenberg, using data from the U.S. Collaborative Perinatal Project, found that family history of seizures, maternal illness during pregnancy, and several perinatal complications — including low Apgar score, birth weight of 2,500 g or less, and feeding problems — were associated with an increased, though generally modest, risk of febrile seizures, and concluded that no single complication of labour or delivery was a dominant risk factor (2) A Danish cohort study by Vestergaard et al. reported that prenatal exposure to maternal cigarette smoking was associated with a significantly increased risk of FS in the offspring, while exposure to alcohol and coffee showed weaker associations (3).

Iron status in infancy has also attracted attention as a modifiable perinatal/early-life factor: Daoud et al. found iron deficiency to be significantly more common among children with a first febrile seizure than among controls (4), a finding corroborated by subsequent systematic reviews and meta-analyses reporting a consistent association between iron-deficiency anaemia and FS (5,6). Using a large Dutch birth cohort, Visser et al. demonstrated that fetal growth restriction, reflected in lower birth weight for gestational age, was associated with a higher risk of febrile seizures in early childhood (7), lending support to the hypothesis that adverse intra-uterine conditions may programme later seizure susceptibility.

### 2.2 Regional Studies

Within the Middle East and neighbouring regions, several case-control studies have specifically examined perinatal antecedents of the first SFS. A prospective case-control study conducted in Sulaimani, Iraq, matching 100 children with a first SFS to 100 age- and sex-matched febrile controls, found significant associations between the first FS and prematurity, low birth weight, caesarean delivery, and bottle feeding, while exclusive breastfeeding appeared to be protective (8). A similarly designed Iranian case-control study reported that caesarean section, together with family history of FS and family history of epilepsy, was significantly more frequent among children with febrile seizures than among febrile controls (9).

Findings from Turkey and Saudi Arabia broadly echo these observations. A Turkish retrospective study identified early perinatal adversity alongside family history as important antecedents of subsequent seizure disorders following an initial a FS (11), while a Saudi study of children admitted with febrile seizures reported a substantial proportion of recurrence and highlighted younger age at onset as a key clinical risk factor, though perinatal variables were less consistently significant in that population (12). An Indian hospital-based study similarly documented a male predominance and a younger age at onset as risk markers among children aged 6–60 months admitted with FS, with a minority having a positive family history (10).

### 2.3 Local (Sudanese) Studies

A structured search of the available literature did not identify any published hospital-based study from Sudan that has specifically examined the association between perinatal factors and SFS in children. This scarcity of locally generated evidence mirrors a broader gap noted in regional reviews of childhood neurological disorders, in which data from sub-Saharan and North-East African settings remain comparatively limited relative to Asia, Europe and the Middle East (13). This absence of local data underscores the need for the present study, which aims to generate the first hospital-based evidence on this association from Northern State, Sudan.

## 3. Materials and Methods

### 3.1 Study Design

Analytic cross sectional study.

### 3.2 Study Area

The study will be conducted at Dongola Hospitals, the main referral hospital of Northern State, Sudan, which provides paediatric emergency, outpatient, and inpatient services to the population of Dongola locality and surrounding areas.

### 3.3 Study Period

The study will be conducted from 20 September 2026 to December 2026, according to the approved research schedule. Data collection will take place from 4 to 22 October 2026.

### 3.4 Study Population

The study population will consist of children aged 6–60 months presenting to Dongola Hospitals with SFS during the data-collection period.

#### 3.4.1 Inclusion Criteria

- Age between 6 and 60 months.
- Documented fever of 38°C or higher at, or immediately before, presentation.
- For cases: a generalized seizure lasting less than 15 minutes, occurring only once in 24 hours, with no evidence of central nervous system infection, acute metabolic derangement, or prior history of a FS.
- Parent or legal guardian available and willing to provide written informed consent.

#### 3.4.2 Exclusion Criteria

- Known epilepsy or other pre-existing neurological or developmental disorder.

- Clinical or laboratory evidence of central nervous system infection or severe electrolyte disturbance.
- Incomplete or unavailable antenatal/perinatal records and an informant unable to recall this history.

### 3.5 Sample Size

The sample size is calculated using the single-population proportion formula: $n = Z^2p(1-p)/d^2$. Using Z = 1.96 for a 95% confidence level, p = 50% because there is no reliable local estimate, and d = 5% margin of error gives n = 384 participants. Adding 10% for non-response or incomplete information gives an adjusted sample size of 427 participants.

$n = Z^2\ p(1 - p) / d^2$

Where: Z = 1.96 for a 95% confidence level; p = 50% (0.50), used because there is no reliable local estimate for the prevalence of the selected perinatal factors among children with simple febrile seizures; and d = 5% (0.05) margin of error.

$n = (1.96)^2 \times 0.50 \times 0.50 / (0.05)^2 = 384$ participants.

Allowing 10% for non-response or incomplete information:

Adjusted sample size = 384 / (1 − 0.10) = 426.7 ≈ 427 participants.

Therefore, the minimum target sample size will be 427 children with SFS. If the number of eligible children presenting during the data-collection period is smaller than 427, all eligible children will be included and the achieved sample size will be reported.

### 3.6 Sampling Technique

A consecutive non-probability sampling technique will be used. Every eligible child aged 6–60 months presenting with a SFS during the data-collection period will be enrolled consecutively until the required sample size is reached. If fewer eligible children are available during the study period, all eligible children will be included and the achieved sample size will be reported.

### 3.7 Data Collection Tools

Data will be collected using a pre-tested, structured, interviewer-administered questionnaire, prepared in English and translated into Arabic with back-translation to verify accuracy. The questionnaire will cover: (a) socio-demographic characteristics; (b) seizure characteristics (for cases); (c) antenatal history, including maternal illness and number of antenatal care visits; (d) perinatal/delivery history, including mode of delivery, place of delivery, gestational age, birth weight, Apgar score, history of birth asphyxia, neonatal jaundice, and NICU admission; (e) postnatal and feeding history, including duration of exclusive breastfeeding; and (f) family history of FS or epilepsy. Where available, information will be cross-checked against antenatal cards and hospital delivery/neonatal records to minimise recall bias.

### 3.8 Data Management and Analysis

Completed questionnaires will be checked daily for completeness, coded, and entered into IBM SPSS Statistics (version 26 or later). Data will be cleaned and validated prior to analysis. Descriptive statistics will be used: frequencies and percentages for categorical variables, and means with standard deviations (or medians with interquartile ranges when appropriate) for continuous variables. The frequency and distribution of each selected perinatal factor will be presented among the study participants. Where an exploratory comparison is appropriate, categorical variables may be compared using Chi-square or Fisher's exact test; however, the primary analysis will remain descriptive and no causal inference will be made.

### 3.9 Ethical Considerations

- Ethical clearance will be obtained from the Faculty of Medicine Research Ethics Committee, University of Dongola, and administrative approval will be sought from the Dongola Hospital administration prior to data collection.
- Written informed consent will be obtained from the parent or legal guardian of every participating child before enrolment.
- Participation will be voluntary, and families will be free to withdraw at any stage without any effect on the care provided to their child.
- Data will be anonymised using study codes, and all collected information will be kept confidential and

stored securely, accessible only to the research team.
- The study is purely observational, involving no additional intervention or risk beyond routine clinical care, and findings will be shared with the hospital administration and relevant health authorities to inform local practice.

## 4. Work Plan & Timeline

The following Gantt chart outlines the main research activities spanning approximately sixteen weeks. Timings may be adjusted based on administrative and ethical approval dates:

| Task to be performed | W1 | W2 | W3 | W4 | W5 | W6 | W7 | W8 | W9 | W10 | W11 | W12 | W13 | W14 | W15 | W16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Proposal submission (20–24 Sep 2026) | ■ | | | | | | | | | | | | | | | |
| Proposal presentation (27 Sep–1 Oct) | | ■ | | | | | | | | | | | | | | |
| Data collection (4–22 Oct) | | | ■ | ■ | ■ | | | | | | | | | | | |
| Data analysis (25 Oct–5 Nov) | | | | | | ■ | ■ | | | | | | | | | |
| Writing results & discussion (8–19 Nov) | | | | | | | | ■ | ■ | | | | | | | |
| Writing final report (22 Nov–3 Dec) | | | | | | | | | | ■ | ■ | | | | | |
| Electronic submission to Dept. of Community Medicine (6–10 Dec) | | | | | | | | | | | | ■ | | | | |
| Research refereeing (13–24 Dec) | | | | | | | | | | | | | ■ | ■ | | |
| Revisions / modifications (27–31 Dec) | | | | | | | | | | | | | | | ■ | |
| Research defense (3–4 Jan 2027) | | | | | | | | | | | | | | | | ■ |

W = week (Sunday–Thursday). W1: 20–24 Sep 2026 · W2: 27 Sep–1 Oct · W3: 4–8 Oct · W4: 11–15 Oct · W5: 18–22 Oct · W6: 25–29 Oct · W7: 1–5 Nov · W8: 8–12 Nov · W9: 15–19 Nov · W10: 22–26 Nov · W11: 29 Nov–3 Dec · W12: 6–10 Dec · W13: 13–17 Dec · W14: 20–24 Dec · W15: 27–31 Dec · W16: 3–4 Jan 2027.

## 5. Budget Outline

Amounts below are illustrative estimates in Sudanese Pounds (SDG) and should be adjusted to reflect current local prices before submission.

| Item | Quantity | Unit Cost (SDG) | Total (SDG) |
|---|---|---|---|
| Stationery & printing (proposal, questionnaires, report) | — | — | 15,000 |
| Questionnaire duplication (250 copies) | 250 | 40 | 10,000 |
| Transportation (research team, field visits) | — | — | 25,000 |
| Data collector / interviewer allowance | 2 collectors × 4 months | 20,000 | 160,000 |
| Statistician consultation (data analysis support) | 1 | 30,000 | 30,000 |
| Communication (airtime, internet) | — | — | 8,000 |
| Data entry & software costs | — | — | 12,000 |
| Contingency (≈10% of subtotal) | — | — | 26,000 |
| Grand Total | | | 286,000 |

## 6. References (Vancouver Style)


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