Synopsis of the Protocol: Global Neuro-Infections Outcome Study (GNIOS)

Introduction

Central nervous system (CNS) infections pose a significant global health burden, especially in low- and middle-income countries (LMICs), where infectious diseases are prevalent. These infections often lead to severe complications requiring surgical intervention. The Global Neuro-Infections Outcome Study (GNIOS) aims to map the burden, spectrum, and outcomes of surgical care for patients with de novo CNS infections across various geographic and socio-economic settings. This study addresses the gap in knowledge regarding the surgical management of CNS infections, particularly in LMICs, and seeks to inform strategies for improving care and outcomes.

Study Objectives

Primary Objective:

To describe the profile of patients, both adults and children, presenting with CNS infections requiring neurosurgical management, including patient demographics, clinical characteristics, surgical indications, procedures, and outcomes.

Secondary Objectives:

1. To detail current referral, resource, and management pathways for these patients.
2. To compare indications for conservative management versus surgery.
3. To compare outcomes across different centers, adjusted for case mix and socio-economic factors.
4. To identify targets for future research and health interventions.
5. To examine seasonal variations in CNS infection incidence.

Study Design

GNIOS is a prospective, international, multi-center observational study involving hospitals admitting both adult and paediatric patients with de novo brain or spine infections. The study includes two components:

1. A 60-day prospective cohort study to gather data on surgical consultations and procedures.
2. A retrospective one-year cohort at selected sites to analyse seasonal variations.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Patients with de novo CNS infections requiring surgical consultation or admission to a surgical unit during the study period.

Exclusion Criteria:
- Patients with prior neurological diagnosis or neurosurgical procedures.
- Iatrogenic post-surgical infections.
- Patients with CNS infections not requiring surgical consultation or admission.

Methods

Recruitment and Screening:

Patients will be recruited consecutively during the 60-day period at each participating hospital. Broadcasting signage will inform patients and guardians about the study.

Data Collection:

Data will be collected using electronic case record forms (CRFs) via the REDCAP platform. Each patient will be anonymized and identified by numeric codes. Data validation will be conducted by independent validators at each site.

Statistical Analysis:

Continuous variables will be described using means and standard deviations or medians and interquartile ranges. Statistical models will be adapted based on the event rate and will be detailed in a pre-written analysis plan.

Ethical Considerations:

Ethics approval will be obtained locally at each participating site. The study is considered a clinical audit with minimal risk, we aim for individual patient consent to be waived to maximize inclusion and avoid bias. Broadcasting documents will be used to ensure transparency and awareness among patients and their families.

Expected Outcomes and Benefits

The study aims to provide comprehensive data on the surgical management and outcomes of CNS infections, highlighting regional disparities and identifying areas for improvement. The findings will inform strategies to enhance surgical care and resource allocation, ultimately aiming to reduce morbidity and mortality associated with CNS infections globally.