**RESEARCH PROTOCOL**

**The Effectiveness of Regional Anaesthesia in the Management of Chronic Pain at Universitas Academic Hospital Pain Unit**

**By**

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**MBChB**

Protocol for a research project submitted in fulfilment of the requirements for the degree

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**1.** **Background**

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage.1,2 Pain is an extremely subjective experience which to varying degrees, may be influenced by biological, psychological and social factors. The concept of pain is learnt through life experiences. Whilst pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being if left uncontrolled.1

Acute pain is usually provoked by a specific disease or injury. It is self-limiting and serves a protective function. It influences behaviour in attempts to avoid further tissue damage and limits movement to assist healing.2 However, acute pain that is ineffectively treated causes

changes in the central and peripheral nervous systems that sustain persistent pain independent of the primary provoking insult.2

Chronic pain is defined as pain that persists beyond the normal time expected for tissue healing, usually more than 3 months and is without apparent benefit.3 It is now considered a disease state.2 Chronic pain may be further divided as associated with or not associated with terminal illness based on treatment purposes.

Chronic non-malignant pain is significantly prevalent, generating suffering, limitation of daily activities and reduced quality of life. It is estimated that 25–30% of the world’s adult population will suffer from chronic pain during their lifetime.2 Generally, the prevalence is higher among women, elder individuals and those with mental stresses, depression and anxiety.1,4 In a significant percentage of those with chronic pain, the etiology is indeterminate.4

Treatment modalities for these patients are associated with inconsistent results and only modest relief in symptoms when effective.5,6 It is therefore a cause of long-term morbidity and varying extents of disability. Consequently, the primary goals of chronic pain management focus on discovering a cause, alleviating suffering and restoring function.6

Therefore, treatment needs to be approached more wholistically, extending beyond solely providing pain relieving medication. Effective management should encompass a multimodal strategy with both pharmacological and nonpharmacological modalities tailored specifically to the individual patient.6

It has been found that patients with chronic pain are often “over-treated” with analgesics or use them inappropriately.2 Opiods are no longer the preferred management strategy.2 Salduker et al have recently found physical, psychological and behavioural therapies to be burdensome to patients, requiring frequent visits at healthcare centers.2

Pain management guidelines emphasize the use and prescribing of rational combination therapy using the least number of medications as necessary.7 Interventional pain management has shown dramatic growth with the utilization of invasive pain management techniques including trigger point injections, intra-articular injections and nerve blocks.5 These have been shown to provide significant pain relief.

Universitas Academic Hospital (UAH) Pain Unit provides services to an array of patients with varying intensities of chronic pain and functional limitations, where patient satisfaction is of utmost importance. These patients are managed with a range of oral analgesics depending on their individual requirements. They are also given the benefit of regional pain management in the form of either trigger point injections; facet joint, nerve and caudal blocks. These are usually performed under radiological or ultrasound guidance.

This study is designed to indicate the effectiveness of regional anaesthetic techniques in managing chronic pain the UAH Pain Unit.

**2.** **Aim**

To determine the effectiveness of regional pain management for the treatment of chronic pain at the Universitas Academic Hospital Pain Clinic.

**3.** **Objectives**

1. To establish the prevalence of effectiveness of regional analgesia by analysing patient satisfaction scores post-intervention, during follow up consultation. Clinically effective treatment will be assessed as a 30% reduction in pain (or >2points on a 0 – 10 numerical rating scale).
2. To analyse the duration of pain relief from regional analgesic techniques.

**4.** **Methods**

**a.** **Population**

Patients will be selected based on their attendance to the Pain Clinic at Universitas Academic Hospital (UAH). These patients are seen for initial consultation by referral. Referrals for evaluation are made by primary care providers and specialists, including neurologists, rheumatologists, orthopaedic surgeons, neurosurgeons and anaesthetists.

**b.** **Inclusion Criteria**

Patients 18 years and over undergoing treatment for chronic pain at UAH pain clinic and who have received treatment for a period greater than 3 months will be included in the study.

**c.** **Exclusion Criteria**

Patients with data collection forms that are inaccurately filled or incomplete data sheets.

**d.** **Study Design and Timeframe**

This study involves a retrospective review. Data will be retrospectively collected from patients’ files at UAH Pain Clinic. This will include data from February 2019 until 30 November 2021.

**e.** **Data Collection**

Patients that attend the UAH Pain Clinic usually follow up for consultation and treatment over 3 month intervals. It has become standard practice since February 2019 that upon return, patients that have received an intervention for pain management are interviewed and questioned using a proforma (appendix A) that is attached to the patient’s file. Included in the proforma is the date of the procedure, type of procedure performed, indication for the procedure, pain score (scale between 1 – 10) before the procedure, percentage pain relief after the procedure and duration of pain relief.

These data from the proforma in the patients’ files will be collected and compiled for analysis.

**Pilot study**

**5.** **Statistical Analysis**

An excel file will be sent to the biostatistician for analysis. For descriptive statistics, categorical data will be summarised into frequencies and percentages, while for numerical data, we shall use means and standard deviations for normally distributed data and median and interquartile ranges for skewed data.

**6.** **Ethical Considerations**

The protocol will be submitted for ethics approval to the Health Sciences Research Ethics Committee at the University of the Free State. An application will be submitted to the Free State Department of Health for provincial approval to conduct the study at the Universitas Academic Hospital.

**7.** **Study Limitations**

Subjectivity of pain scores and variation of pain threshold amongst individuals.

**8.** **Intended Project Schedule**

|  |  |
| --- | --- |
| Apply for ethics approval (4 weeks) | January 2022 |
| Apply for Free State Department of Health approval (4 weeks) | February 2022 |
| Data collection | March 2022 |
| Biostatistics data analysis | April 2021 |
| Complete final manuscript | May 2021 |

**9.** **Proposed Budget**

There will not be any cost incurred during the undertaking of this project.

**10. References**

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**11. Appendix**

**a.** **Patient Follow Up Questionnaire**