**Post-dural puncture headache**

**following**

**lumbar puncture with/without**

 **intrathecal chemotherapy,**

**How long should patients remain recumbent?**

**A Pilot Randomised Controlled Trial**

**(The PLANE Study)**

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# SYNOPSIS

At the Royal Brisbane and Women’s Hospital (RBWH), procedure mandates that patients lie flat for two (2) hours following a lumbar puncture (LP) with or without intrathecal (IT) chemotherapy. The focus in the Oncology Day therapy Unit (ODTU) is on patient satisfaction and the desire to enhance nursing practice in the care of patients diagnosed with cancer. A systematic review of literature was completed as part of a 12-week Evidence-Based Practice programme to investigate the risks and benefits of patients lying flat for one (1) hour versus two (2) hours following IT chemotherapy via LP. This systematic review found no studies that met the inclusion criteria, therefore the criteria were expanded to include patients requiring diagnostic LPs. Two studies were included (Tejavanija, 2006; Kim, 2012). There was no difference in the incidence of post-dural puncture headaches. This pilot study will randomise patients to lie flat for two (2) hours in the control group and one (1) hour in the treatment group.

The process through which an LP is performed heightens the risk of post-dural puncture headache (PDPH) relating to cerebral spinal fluid (CSF) leakage (Ahmed, 2006; Baumgarten, 1987; Davignon, 2002; Denny, 1987; Harrington, 2004). To monitor this outcome, this research will introduce an LP Nursing Assessment Tool which will include the sub-category of headache pain in the nurse-lead patient assessment prior to and following LP, facilitating best practice in patient care, as well as having the potential to influence patient satisfaction. The LP Nursing Assessment Tool will include a follow-up phone call from a Research Nurse (ReN) 48 hours after the LP to conduct an over-the-phone assessment, thus promoting nurse-lead patient care. Education will be provided to nursing staff in the implementation of the LP Nursing Assessment Tool to improve adherence to documentation of the procedure performed and patient outcomes.

##

## BACKGROUND

Patients with a haematological malignancy may require a LP for IT delivery of cytotoxic medication (Olmos-Jiménez, et al 2017). Following an LP, it is a requirement for the patient to remain in a supine position for a period of time to facilitate the sealing of the puncture site, as well as protecting against potential PDPH (Gaucher & Perez, 2002). For LP’s performed in an outpatient setting, the time required for the patient to remain supine may impact on patient satisfaction, length of stay and occasions of service. It is not clear if time remaining supine impacts on outcomes such as patient reported PDPH and its severity. Our procedure mandates that patients lie flat for two (2) hours following an LP with or without IT chemotherapy.

In an oncology setting, therapeutic LPs are performed on patients for diagnostic purposes and to administer IT chemotherapy. Following an LP, it is recommended that the patient remain in a prone position for one (1) hour to assist in the distribution of the chemotherapy through the cerebral spinal fluid (CSF) (Blaney, et al, 1995) and to protect against potential PDPH (Giebel, et al, 2008) through leaking of CSF through the puncture site in the dura (Ahmed, 2006; Baumgarten, 1987; Davignon, 2002; Denny, 1987; Harrington, 2004). For LPs performed in an outpatient setting, the time required for the patient to remain supine may impact on patient satisfaction, length of stay and occasions of service. It is not clear if time remaining supine impacts on outcomes such as patient reported PDPH and its severity (Ching-Hon & Howard 2008).

A systematic literature review and meta analysis of published articles and randomised controlled trials without date restrictions was performed. Electronic database searches of PubMed, CINAHL Embase and Cochrane Library using key words: lumbar, dural, intrameningeal, intraspinal, intra-spinal, puncture, intrathecal, chemotherapy, carcinochemotherapy, antileukaemia, antileukemia, methotrexate cytarabine, haematology, hematology, leukaemia, leukemia, malignancy, cytotoxic, antineoplastic, position, plane, supine, recumbent, hour, procedure, policy, practice, guideline. The search was limited to English language and human subjects.

No studies compared duration of lying supine following IT administration of chemotherapy via LP and relationship to PDPH. Therefore, inclusion criteria were modified. Two studies in neurological populations were included reviewing time recumbent following LP and prevalence of PDPH. LPs were performed for diagnostic purposes in both studies. There was no difference in number of patients reporting PDPH following LP in either the ≤1 hour recumbent group or the >1 hour recumbent group (Risk Ratio 1.07; Confidence Interval [CI] 95%, 0.60-1.93; P=0.61, ≤1 hour 17/67; 25% vs >1 hour 16/68; 24%). Reduction in severity of PDPH was demonstrated in the ≤1 hour recumbent group (Mean Difference -0.64; CI 95%, -1.16 to -0.12, P=0.02) (Tejavanija, et al, 2006. Kim et al, 2012).

There is a need for improved documentation to facilitate best practice nursing and provide guidance in caring for patients receiving IT chemotherapy via LP (Destrebecq et al, 2014). Additionally, it is a nursing responsibility to ensure that patients understand the potential risks that may occur following an LP and to know when and how to contact medical support following discharge (DeVesty, 2018).

As evidenced above, the paucity of information available is insufficient to modify current practice of patients required to lie flat for two (2) hours following IT chemotherapy via LP. Therefore, further research is necessary in order to provide best practice, evidence-based nursing care in responding to the needs to patients prior, during and following IT chemotherapy via LP.

## METHODS

## RESEARCH AIMS AND OBJECTIVES

This research aims to provide an evidence base for the length of time patients need to lie flat after diagnostic and therapeutic LPs on the prevalence of PDPHs. Currently, the *Lumbar Puncture – Adult* Procedure states “the patient should lie flat for 2 hours” after an LP and continue to remain lying flat to manage PDPH, when incidence of PDPH is directly related to the size of the needle (Boon et al, 2004). This recommendation is not supported by evidence. This study aims to assess the feasibility of the proposed study design and procedures, which will facilitate the implementation of a definitive non-inferiority randomised controlled trial (RCT). The research objectives are:

1. To determine the feasibility of recruiting, randomising and retaining participants.
2. To facilitate the estimation of effect size for use in a definitive non-inferiority RCT based on the prevalence of PDPH as the primary outcome.

If demonstrated that the required time for patients to lie flat following LP with/without IT chemotherapy of one (1) hour or less has no difference on the prevalence on patient reported PDPH, this would translate into improved patient flow and the associated cost benefits. This would result in increased patient satisfaction with a co-contributing factor being focussed nursing care and assessment.

Through this pilot study best nursing practice will be promoted in the implementation of the LP nursing assessment tool (See Appendix Two) encompassing pre-procedure assessment including, (i) LP history, (ii) Common Toxicity Criteria (CTC) symptom assessment, (iii) review of blood pathology, (iv) review of current medications, (v) observations, (vi) headache, (vii) sedation, (viii) oral intake and (ix) LP procedure. Post-procedure assessment is addressed with a score rating attributed to patient status for (x) vital signs, (xi) activity and mental status, (xii) headache, (xiii) surgical bleeding, (xiv) pain, nausea and/or vomiting and (xv) intake and output. This score is tallied and forms part of a discharge assessment which also includes, (xvi) falls risk assessment, (xvii) GCS score, (xviii) limb power/sensation present, and (xix) check boxes for items of which a Discharge Information Sheet is one. The LP nursing assessment tool also guides nurses in conducting an over-the-phone assessment with the patient 48 hours following the LP, providing an opportunity to link into Tier 2 Medicare funding.

**Primary Outcome**

The feasibility of conducting an RCT to evaluate prevalence and/or severity of PDPH in patients after lying supine for either one (1) hour or less versus greater than one (1) hour following LP with/without IT chemotherapy.

**Secondary Outcome**

The prevalence of PDPH following LP with/without IT chemotherapy, and severity of PDPH experienced (symptoms experienced and the timing of onset) and patient satisfaction.

## TYPE OF STUDY

This is a parallel group, pragmatic pilot RCT to assess the feasibility of a definitive RCT comparing ≤1 hour lying supine following LP with/without intrathecal chemotherapy to 2 hours lying supine (current practice) following LP with/without intrathecal chemotherapy on the prevalence of PDPH.

## HYPOTHESIS

This pilot RCT will demonstrate feasibility of an adequately powered RCT of equivalence design.

## SAMPLE AND SETTING

The RBWH Cancer Care Services currently perform 200 no. diagnostic and/or therapeutic LP per annum. The LP will be the unit of analysis. It is anticipated that approximately 55 no. LP procedures will be randomly selected where the patient remains recumbent for a period of ≤1 hour with 55 no. for a period of 2 hours post-LP. The study would be conducted within RBWH Cancer Care Services in Oncology Day Therapy Unit, Oncology Procedure Unit and Ward 5C [Haematology and Haematopoietic Stem Cell Transplantation (HSCT) Unit].

**Sample size and justification**

There is no standard guideline on sample size calculation for a pilot RCT (Hertzog, 2008). We plan to recruit 110 subjects (55 per group), the unit of analysis is the LP.

## SELECTION CRITERIA

All patients presenting to RBWH Cancer Care Services for LP and addressing the following inclusion and exclusion criteria will be considered for participation in this pilot RCT.

## INCLUSION CRITERIA

1. Haematology inpatients and outpatients requiring LP for either diagnostic and/or therapeutic purposes.

## EXCLUSION CRITERIA

1. Language or cognitive barrier to consent.
2. Pregnant women
3. Under 18 years.

**RECRUITMENT, RANDOMISATION, ALLOCATION CONCEALMENT AND BLINDING**

A Research Nurse (ReN) will screen and gain consent from inpatients and outpatients requiring LP within Cancer Care Services in Outpatients Procedure Unit (OPU), Oncology Day Therapy Unit (ODTU) and Ward 5C – Haematology and HSCT Unit. Randomisation will be via a telephone-based service to conform with best practice standards for randomisation generation and allocation concealment until study entry. Randomisation will be on a 1:1 ratio between groups with randomly varied block sizes. An ReN will contact the patient 48 hours following the LP and conduct a telephone assessment as per the LP Nursing Assessment Tool. Data will be collected through completed LP Nursing Assessment Tool, patient notes and pharmacy medication summaries. Due to the nature of the study, it is not possible to blind participants and research investigators.

# DATA COLLECTION

## Baseline

***Patient demographics will be collected at baseline:***

1. Age
2. Gender
3. Weight and height / BMI.
4. Disease / Diagnosis
5. Co-Morbidities
6. Protocol
7. Patient self-reported history.
8. Prior experience of post-dural puncture headache (PDPH).

## On day of LP

***Patient assessment prior to LP:***

 **Pre-Procedure**

1. LP History including history of previous PDPH.
2. CTC including nausea and vomiting, peripheral neuropathy, etc.
3. Blood tests.
4. Medications.
5. Observations
6. Headache
7. Sedation
8. Oral Intake
9. LP procedure – Details and time.

**Post-Procedure**

1. Patient mobilised – Time.
2. Observations
3. Headache
4. Review of LP site.
5. Pain, nausea and/or vomiting.
6. Oral intake and voiding.
7. Falls risk assessment.
8. GCS
9. Limb power/sensation present.
10. Discharge patient information.

## 48 Hours after LP – By telephone call to patient from RN.

1. Headache and, if experienced, type, pain scale and interventions taken.
2. LP site.
3. Activity and mental status.
4. Oral intake.
5. Bowel/bladder function.

### To be collected ONE (1) MONTH AFTER PROCEDURE

* + Reflective survey on patient satisfaction (See Appendix Two).

# ANALYSIS PLAN

## Primary Outcome

Analysis of feasibility will be based on the following measures:

1. Recruitment: ≥ 80% Of eligible patients agree to enrol;
2. Retention and attrition: < 15% Of participants are lost to follow-up or withdraw from study;
3. Protocol adherence: ≥ 80% Of participants receive their allocated treatment throughout their study participation;
4. Missing data: <10% Of data are missed during study data collection;
5. Satisfaction and acceptability: to patients, carers and healthcare staff levels; and
6. Sample size estimates: For future equivalence trial.

Feasibility outcomes will be analysed using descriptive statistics (Thabane, 2010). Based on the analysis of feasibility, we will determine if a future larger study is feasible as is, feasible with minimal changes or not feasible (Thabane, 2010). The limited sample size of this study (n=110) will not allow for statistical analysis to be performed with sufficient power. However, we will pilot our analytical plan (Thabane 2010; Lancaster, 2004).

## Secondary Outcomes

Prior to analysis, data cleaning of outlying figures, missing and implausible data will be undertaken, and a random 5% sample of source data will be re-entered and checked. All randomised patients will be analysed on an intention-to-treat basis. Comparability of groups at baseline will be assessed using clinical parameters. Incidence rates of PDPH, severity of PDPH and patient satisfaction will summarise the impact of the control and intervention group differences using 95% confidence intervals and p values. Secondary outcomes will be compared between groups using parametric or nonparametric techniques as appropriate.

**LIMITATIONS OF THE RESEARCH**

Limitations that may be encountered are confounders including, but not limited to, the use of sedation during the procedure, incomplete data collection by nursing staff, the inability to blind nurses and patients to the intervention, and small sample size.

## PRECISION

Precision through 1:1 recruitment will provide equal distribution of patient population receiving an LP with/without IT chemotherapy.

## VALIDITY

### Internal

This pilot study is a single centre study conducted at Cancer Care Services, RBWH, Herston, ensuring consistency and continuity in recruitment and data collection and analysis. Pre-procedure assessment will be conducted prior to each LP. This will ascertain the existence of pre-existing headache and pain scale rating of same, as well as previous history of headache following an LP with/without IT chemotherapy. Furthermore, a baseline set of observations and common toxicity criteria (CTC) symptom assessment will be performed by an RN to establish pre-existing symptoms which are also associated with PDPH.

The nursing assessment tool will apply to both the control group and the experimental group. Patients assigned to the control group will be required to remain lying flat for two (2) hours (current practice). Those patients in the experimental group will remain lying flat for one (1) hour.

### External

RBWH is a quaternary public hospital whose patient population is representational of many ethnicities. However, with the small sample size of this pilot study, the group treated may not be generalisable to another population.

## TIME FRAME

110 Patients requiring an LP with/without IT chemotherapy will be selected for this pilot study. The LP will be the unit of analysis as patients may require multiple LPs during their treatment protocol. It is anticipated that it would take approximately six (6) months to recruit the patients undergoing these LPs. An additional six (6) months would be required for data collection, data cleaning and analysis. A diagrammatic timeline is set out below:

|  |
| --- |
| **MONTH** |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** |
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| **LEGEND** |
| **ACTIVITY** | **INDICATOR** |
| Apply for funding, ethics approval and governance |  |
| Education & training, implementation of nursing assessment tool |  |
| **RECRUITMENT** of study participants |  |
| Data Analysis |  |
| Write up publication & CNSA presentation |  |

**FUNDING**

Research grant applications have been successful with this project now being supported by Hornery and RBWH Cancer Care Services Fund, The Rosemary Bryant Foundation Accelerator Grant and RBWH Foundation 2019 Diamond Care Grant.

This pilot study is supported by ODTU and the nursing team. An ODTU nurse is off-line to complete the 12-month Evidence-Based Research Internship occurring one (1) day per week with support from the Nursing Research Department and funded through RBWH Cancer Care Services.

## MANAGEMENT OF DATA

All data collected in relation to the pilot study will be kept in a secure locked cabinet located within the premises of the Centre of Clinical Nursing, RBWH Campus, Herston.

The management and storage of data in this project will conform to the requirements the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007) guidelines. No identifying participant information will be recorded on the online platforms. Participant confidentiality will be assured. All electronic data will be de-identified and collected on a password protected database. A screening log will be kept independently from the electronic database and stored in a locked filing cabinet in a locked room. Fifteen years after results are finalised, electronic files and paper documents will be destroyed (NHMRC, 2015). Data used in publications will be de-identified and reported as group data to ensure confidentiality.

**ETHICAL CONSIDERATIONS**

This research will be reviewed by the RBWH Human Research and Ethics Committee (HREC). The trial will be registered with the Australian and New Zealand Clinical Trial Registry. Adverse events will be recorded and serious adverse events to the RBWH HREC.

**DISSEMINATION OF RESULTS**

The results of this research will be disseminated within the RBWH, and at relevant local, national and international oncology scientific meetings. The pilot study will be published in a relevant healthcare journal and written in accordance with the CONSORT statement recommendations.

**ADVERSE EVENTS**

Adverse events occurring concurrently or as a result of the LP would be addressed in accordance with RBWH policies, procedures and guidelines. Serious adverse events, such as death and unplanned admissions to hospital or the intensive care unit, will be reported to the RBWH HREC.

# DEFINITIONS

**Chemotherapy** – treatment involving the use of chemical agents (Harris, et al, 2014, p. 339).

**Intrathecal** (IT) – relating to location of “structure, process or substance within a sheath”, with reference to the spinal canal for the purposes of this protocol. (Harris, et al, 2014, p. 923).

**Lumbar Puncture** (LP) – a medical procedure undertaken by qualified health professionals for diagnostic and/or therapeutic purposes whereby a fine gauge needle is inserted through the dura mater into the cerebrospinal fluid (CSF)-filled subarachnoid space (Bezov, et. al, 2010, p. 1144)

**Post-Dural Puncture Headache** (PDPH) – also referred to as “post lumbar puncture headache”. According to the International Headache Society (2018), PDPH is a headache which “occurs within 5 days of a lumbar puncture, caused by cerebrospinal fluid (CSF) leakage through the dural puncture.”. PDPH may be associated with neck stiffness, hearing changes, visual disturbances, photophobia, and nausea. (“7.2.1 Post-dural puncture headache”, IHS Classification ICHD-3, 2018) (Bezov, et al, 2010, p. 1145).

**Recumbent** – to be “lying down”. (Harris, et al, 2014, p. 1480).

**Supine** – to lie flat on back with head and palms of hands facing upwards (Marcovitch, 2005, p. 685).

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# APPENDIX ONE

## STANDARD OPERATING PROCEDURES

(Refer RBWH Procedure 001727: Cytotoxic Drug Administration – Effective from: August 2017)

(Refer RBWH Procedure 001530: Lumbar Puncture – Adult – Effective from: June 2017)

# APPENDIX TWO

## PROFORMA

(Refer Lumbar Puncture Diagnostic/Therapeutic Nursing Assessment Tool – attached under separate filename: MR A 8875 Lumbar Puncture (LP) Diagnostic Therapeutic Nursing Assessment Tool TRIAL 181113)

(Insert Discharge Information – attached under separate filename: Post Lumbar Puncture Discharge Advice)

(Insert PDPH Pilot Study Patient Satisfaction Survey – attached under separate filename: PDPH IT Chemo LP Patient Satisfaction Survey)