一、 請將下列出自：**Slight, C., Marsden, J., & Raynel, S. (2009). The impact of a glaucoma nurse specialist role on glaucoma waiting lists. Nursing Praxis in New Zealand. 25(1):38-47.**之英文摘要，逐字翻譯成中文（25%）

Over the last two decades there has been an increasing demand on health care services. This has led to increased waiting lists and waiting times to access public hospital services. In ophthalmic practice an aging population and technological advances have been major contributors to this situation. The challenge for health care providers is how to manage waiting lists within the resources provided and targets set by Elective Services, a department of the Ministry of Health (MoH). The Ministerial Taskforce on Nursing (1998) highlighted that nurses are an underutilised resource. Subsequent to the Ministerial Taskforce, the availability of interim funding from Elective Services and a skilled speciality nursing workforce the Ophthalmology Department at a large metropolitan hospital was able to implement an advanced nursing role with respect to glaucoma management. Early diagnosis is important in reducing the risk of permanent visual impairment from primary open angle glaucoma; therefore the length of time to diagnosis can have long term implications for the patient. Patients for the 'nurse-led' glaucoma clinic were recruited from specific categories of glaucoma patients on the waiting list. An audit of the impact on the waiting list was undertaken periodically over a two year period. The audit following the introduction of the clinical nurse specialist clinic shows a marked reduction in waiting list numbers and length of time waiting for first specialist assessment for glaucoma. The implementation of this role proved to be successful and has subsequently become a permanent nurse specialist position in the ophthalmology department.

二、請您就下列所附之一份研究受試者同意書，以研究倫理三大原則：尊重人格(Respect for person)、行善(beneficence)、及公平正義(justice) 為依據來批判此份同意書，回答：

(A) 研究倫理三大原則中包含的內容、項目為何？(9%)

(B) 受試者同意書中哪些項目符合研究倫理，理由為何？(8%)

(C) 不符合的項目請提出修正內容？(8%)

見背面

您被邀請參與此臨床試驗研究。這份表格提供您本研究之相關資訊，研究主持人或研究護士將會為您說明研究內容並回答您的任何疑問。

研究計畫名稱：

中文: 以個管師的照護模式協助神經母細胞瘤病童照顧者面對疾病不確定感調適之成效

英文: The effect of nurse case manager model on caregiver's adaptation of disease uncertainty about their child with neuroblastoma

執行單位：護理學系　　委託單位/藥廠：無

主要主持人：李 xx　　職稱：副教授　　電話：(02)23123456 轉 8xxxx

協同主持人：許 xx　　職稱：主治醫師　　電話：0972-25xxxx

※二十四小時緊急聯絡人：李 xx　　電話：0968-66-xxxx

受試者姓名：　　性別：

出生日期：

病歷號碼：

通訊地址：

聯絡電話：

法定代理人或有同意權人之姓名：　　性別：

與受試者關係：

出生日期：

身份證字號：

通訊地址：

聯絡電話：

一、藥品、醫療技術、醫療器材全球上市現況簡介：

本研究不涉及藥品、醫療技術、醫療器材。

二、試驗目的：

第一年著重在基礎資料的建立、病友會及相關網站的成立、疾病相關衛教手冊的撰寫，並進一步評估病童及主要照顧者的需要，提供適當的措施。評估其就醫的遵從性、心理的壓力和對孩子疾病不確定感。第二年和第三年則是追蹤及後續評估，其就醫的遵從性、心理的壓力和對孩子疾病不確定感，並且繼續依病童及主要照顧者的需要給予適當的措施。

三、試驗之主要納入與排除條件：

➢ 納入條件：符合下列條件者，適合參加本試驗

1. 您的孩童符合第 2-4 點所有條件之父母或主要照顧者。
2. 您的孩童由小兒血液腫瘤科醫師確立診斷為神經母細胞瘤者。

接次頁

3. 您的孩童治療階段可以是初診斷、治療中或已完成治療者。
4. 您是出於自願同意接受問卷調查、訪談及錄音共五次，並願意簽署同意書者。

➢ 排除條件：若有下列任一情況者，不能參加本試驗

1. 您的孩童非診斷為為神經母細胞瘤者。
2. 您不同意參與本研究者。

四、試驗方法及相關檢驗：

您的孩童在每次門診、住院及出院後，由一位專任個案管理師予以探訪、追蹤或解答您的疑問，並且需要您填寫五次問卷與接受訪談，每次填寫問卷的時間大約需要30分鐘，訪談的時間則視您的需要而定，訪談的過程中，為求資料記錄的正確性及完整性我們將會進行錄音，您所提供的任何資料將會被妥善保管及保密，所有檔案在研究結束後將會予以銷毀，更不會造成您及孩子的傷害及影響；而在您參與研究的三年內，專任個案管理師將會持續追蹤您的孩童的就醫情形。

五、可能產生之副作用、發生率及處理方法：

此研究以問卷調查和訪談的方式進行，幾乎不太可能讓您產生身體上的危害。有的話可能是您在填答問卷過程中，因其中問題感到不適，此時，您可以選擇立即停止作答，並且將情況告訴協助填答的研究助理，或是李xx副教授(電話：0968-66-xxxx)，我們將儘量幫助您處理，您可以自由地選擇是否繼續作答。無論您是否完成問卷和訪談，我們都非常感謝您的協助。

六、其他替代療法及說明：

不適用。

七、試驗預期效益：

本研究發展出來的知識：瞭解神經母細胞瘤主要照顧者在面對疾病與治療的衝擊下之調適過程，可以提供作為臨床照護的參考，並提供增設聯合門診與相關醫療資源服務的依據。

八、試驗進行中受試者之禁忌、限制與應配合之事項：

無。

九、機密性：

xx醫院將依法把任何可辨識您的身分之記錄與您的個人隱私資料視為機密來處理，不會公開。如果發表試驗結果，您的身分仍將保密。您亦瞭解若簽署同意書即同意您的原始醫療紀錄可直接受監測者、稽核者、研究倫理委員會及主管機關檢閱，以確保臨床試驗過程與數據符合相關法律及法規要求；上述人員並承諾絕不違反您的身分之機密性。

十、損害賠償與保險：

(一) 如依本研究所訂臨床試驗計畫，因而發生不良反應或損害，本醫院願意提供專業醫療照顧及醫療諮詢。您不必負擔治療不良反應或傷害之必要醫療費用。

(二) 本研究不提供其他形式之補償。若您不願意接受這樣的風險，請勿參加試驗。

(三) 您不會因為簽署本同意書，而喪失在法律上的任何權利。

十一、受試者權利：

(一) 試驗過程中，與您的健康或是疾病有關，可能影響您繼續接受臨床試驗意願的任何重大發現，

見背面

都將即時提供給您。

(二) 如果您在試驗過程中對試驗工作性質產生疑問，對身為患者之權利有意見或懷疑因參與研究而受害時，可與本院之研究倫理委員會聯絡請求諮詢，其電話號碼為：02-2312-3456 轉 63155 。

(三) 為進行試驗工作，您必須接受李 xx 副教授的照顧。如果您現在或於試驗期間有任何問題或狀況，請不必客氣，可與在醫學院護理學系所的李 xx 副教授聯絡 (24 小時聯繫電話：0968-66-xxxx)。

本同意書一式 2 份，李 xx 副教授或研究助理已將同意書副本交給您，並已完整說明本研究之性質與目的。李 xx 副教授或研究助理已回答您有關研究的問題。

十二、試驗之退出與中止：

您可自由決定是否參加本試驗；經考慮同意參加本試驗後，試驗過程中除非必要，請您勿撤銷同意而退出試驗；若需撤銷，請您簡要告知理由。此過程不會引起任何不愉快或影響日後醫師對您的醫療照顧。試驗主持人或贊助廠商亦可能於必要時中止該試驗之進行。

三、 請您閱讀下列簡要之研究計劃，並以中文逐題回答下列問題：

1. 此研究計劃是屬於何種類型的研究設計，並說明此研究計畫的「研究主題、研究對象以及主要目的與次要研究目的」為何？(10 %)
2. 此計劃案的「收案條件與排除條件」各為何？請逐一列出。(15%)
3. 您若為本研究計劃案之研究護理師，您要如何執行相關治療程序以完成整個研究計劃案？其中每位個案將會在何種情況下結案？(25%)

接次頁

PROTOCOL SYNOPSIS

【TITLE】

A Phase I, Multi-Center, Open-Label, Dose Escalation Trial of the Safety and Pharmacokinetics of Intravenous XXX Given with Prophylactic G-CSF in Subjects with Solid Tumors

【SUBJECT POPULATION】

Subjects with histologically or cytologically confirmed solid tumors for whom monotherapy with an investigational agent is appropriate

【PRIMARY OBJECTIVE】

- Determine the maximal tolerated dose (MTD) of XXX (a hypoxia-activated prodrug) when administered with prophylactic G-CSF on an every three week schedule

【SECONDARY OBJECTIVES】

- Characterize the safety of XXX when administered with prophylactic G-CSF
- Evaluate the pharmacokinetics of XXX and its alcohol metabolite
- Evaluate the rate of hypoxia in various solid tumors using F-MISO PET imaging
- Assess for anti-tumor activity
- Collect plasma samples for assessment of potential biomarkers of tumor hypoxia

【INCLUSION CRITERIA】

- Age 18 years or more
- Histologically or cytologically confirmed solid tumor
- Subject must have measurable or evaluable disease
- ECOG Performance Status of 0 or 1
- Ability to read, understand and provide written informed consent
- If the subject is on systemic steroids, the dose of steroids must be stable for at least two weeks prior to the first dose of XXX

【EXCLUSION CRITERIA】

- Greater than 3 myelosuppressive chemotherapy regimens. Subjects with more than 3 prior myelosuppressive regimens who are considered to have adequate marrow reserve based on prior exposure to either: 1) minimally myelosuppressive regimens or; 2) limited cycles of myelosuppressive regimens, may be entered on study pending a discussion between the principal investigator and the sponsor medical monitor
- Licensed or investigational anti-cancer therapy (including radiotherapy) within four weeks of Cycle 1 Day 1 administration of XXX. Subjects on androgen deprivation therapy are allowed on study and may continue to receive androgen deprivation therapy while on study

見背面

- Prior radiotherapy to more than 20% of bone marrow
- Prior high-dose chemotherapy (including either myeloablative or non-myeloablative transplants)
- Absolute neutrophil count of $< 1.5 \times 10^9$/L
- Prothrombin time >1.5 x normal
- Platelet count of $< 100 \times 10^9$/L
- Hemoglobin level of < 9 g/L (or requiring red blood cell transfusions to maintain hemoglobin > 9 g/L)
- Serum bilirubin > 1.5 times the upper limit of normal
- ALT or AST > 5 times the upper limit of normal if liver metastases are present, or > 2 times the upper limit of normal if liver metastases are absent
- Serum creatinine > 1.5 times upper limit of normal
- Less than 24 hours from any prior radiotherapy or the likelihood of toxicity from prior radiotherapy
- Women who are pregnant, breast-feeding or planning to become pregnant during the study
- Men or women of reproductive-potential who are unwilling to use an effective method of contraception during the study and for 30 days following the last dose of study medication
- Evidence of a significant medical disorder or laboratory finding that in the opinion of the Investigator compromises the subject's safety during study participation such as: uncontrolled infection or infection requiring a concomitant parenteral antibiotic; uncontrolled diabetes; congestive heart failure; myocardial infarction within 6 months of study; chronic renal disease; or coagulopathy (excluding prophylactic anticoagulation)
- Less than four weeks since major surgery
- Known to be HIV positive, Hepatitis B surface antigen positive or known to be Hepatitis C positive with abnormal liver function tests

【STUDY DESIGN】

Single arm, phase I, multi-center, open-label, uncontrolled, dose escalation study

【TREATMENT】

All subjects will undergo baseline evaluation with history, physical exams, blood work and disease assessment as appropriate for their tumor type. In addition, subjects will undergo PET imaging with F-18-Fluoro Misonidazole (F-MISO) for assessment of tumor hypoxia. Subjects will receive XXX intravenously once every 21 days along with prophylactic G-CSF. G-CSF will be administered at a standard dose and schedule in all cohorts. The dose of XXX will be increased between cohorts of three subjects each until dose limiting toxicity (DLT) is observed. MTD will be defined using standard phase I study criteria.

Subjects who remain on study beyond cycle one, and who experience minimal toxicity in cycle one, may have their dose level of XXX increased for subsequent cycles. Subjects may continue to receive XXX until demonstration of disease progression or unacceptable toxicity. Pharmacokinetics

接次頁

will be performed during cycle one. A formal tumor assessment will be performed prior to the start of cycle 3.

【STUDY COUNTRY LOCATION】

United States and Taiwan

【TIME PERIOD AND NUMBER OF SUBJECTS】

- Anticipated Starting Date of Study: January 2010
- Anticipated Completion of Study Enrollment: September 2010
- Anticipated Study Analysis: November 2010
- Estimated Number of Sites: 2
- Estimated Number of Subjects: 18 to 21