科目：臨床研究護理學　　　　【題目共四大題，敬請注意答題時間分配】

一、請詳閱下列這段敘述之後，依據其意回答問題： **(本大題未使用中文回答，酌予扣分) (35%)**

【摘錄自 Chataway J, De Angelis F, Connick P, et al. Lancet Neurol. 2020 Mar;19(3):214-225.】

Background: Neurodegeneration is the pathological substrate that causes major disability in secondary progressive multiple sclerosis. A synthesis of preclinical and clinical research identified three neuroprotective drugs acting on different axonal pathobiologies. We aimed to test the efficacy of these drugs in an efficient manner with respect to time, cost, and patient resource.

Methods: We did a phase 2b, multiarm, parallel group, double-blind, randomised placebo-controlled trial at 13 clinical neuroscience centres in the UK. We recruited patients (aged 25-65 years) with secondary progressive multiple sclerosis who were not on disease-modifying treatment and who had an Expanded Disability Status Scale (EDSS) score of 4·0-6·5. Participants were randomly assigned (1:1:1:1) at baseline, by a research nurse using a centralised web-based service, to receive twice-daily oral treatment of either amiloride 5 mg, fluoxetine 20 mg, riluzole 50 mg, or placebo for 96 weeks. The randomisation procedure included minimisation based on sex, age, EDSS score at randomisation, and trial site. Capsules were identical in appearance to achieve masking. Patients, investigators, and MRI readers were unaware of treatment allocation. The primary outcome measure was volumetric MRI percentage brain volume change (PBVC) from baseline to 96 weeks, analysed using multiple regression, adjusting for baseline normalised brain volume and minimisation criteria. The primary analysis was a complete-case analysis based on the intention-to-treat population (all patients with data at week 96). This trial is registered with ClinicalTrials.gov, NCT01910259.

見背面

Findings: Between Jan 29, 2015, and June 22, 2016, 445 patients were randomly allocated amiloride (n=111), fluoxetine (n=111), riluzole (n=111), or placebo (n=112). The primary analysis included 393 patients who were allocated amiloride (n=99), fluoxetine (n=96), riluzole (n=99), and placebo (n=99). No difference was noted between any active treatment and placebo in PBVC (amiloride vs placebo, 0·0% [95% CI -0·4 to 0·5; p=0·99]; fluoxetine vs placebo -0·1% [-0·5 to 0·3; p=0·86]; riluzole vs placebo -0·1% [-0·6 to 0·3; p=0·77]). No emergent safety issues were reported. The incidence of serious adverse events was low and similar across study groups (ten [9%] patients in the amiloride group, seven [6%] in the fluoxetine group, 12 [11%] in the riluzole group, and 13 [12%] in the placebo group). The most common serious adverse events were infections and infestations. Three patients died during the study, from causes judged unrelated to active treatment; one patient assigned amiloride died from metastatic lung cancer, one patient assigned riluzole died from ischaemic heart disease and coronary artery thrombosis, and one patient assigned fluoxetine had a sudden death (primary cause) with multiple sclerosis and obesity listed as secondary causes.

(1-1)請說明本研究設計。(5%)

(1-2)請簡述本研究如何執行隨機分派。(5%)

(1-3)請寫出本研究如何達到試驗盲性。(5%)

(1-4)請寫出本研究之重要發現。(10%)

(1-5)若您是本案之研究護理師，會如何確保試驗收案好品質。(10%)

二、請簡述臨床試驗研究之分期，及各期別之重要研究目的。(15%)

接次頁

三、請闡述臨床研究護理師(CRN)的專業角色與執業職責。(10%)

四、請閱讀下列文章，並**使用中文**回答相關的問題：**(本大題未使用中文回答，酌予扣分)(40%)**

　　Severe primary graft dysfunction (PGD) of grade 3 (PGD3) is a common serious complication following lung transplantation. We aimed to assess physiological donor lung preservation using the Organ Care System (OCS) Lung device compared with cold static storage. In this non-inferiority, randomized, controlled, open-label, phase 3 trial (INSPIRE) recipients were aged 18 years or older and were registered as standard criteria primary double lung transplant candidates. Eligible donors were younger than 65 years old with a ratio of partial pressure of oxygen in arterial blood to the fraction of inspired oxygen of more than 300 mm Hg. Transplant recipients were randomly assigned (1:1) with permuted blocks, stratified by center, to receive standard criteria donor lungs preserved in the OCS Lung device (OCS arm) or cold storage at 4°C (control arm). The composite primary effectiveness endpoint was absence of PGD3 within the first 72 h after transplant and 30-day survival in the per-protocol population, with a stringent 4% non-inferiority margin. Superiority was tested upon meeting non-inferiority. The primary safety endpoint was the mean number of lung graft-related serious adverse events within 30 days of transplant.

(4-1)請描述此研究之目的(10%)

(4-2)請問此研究之複合式主要療效指標為? (10%)

(4-3)文中提到個案是依 randomly assigned 方式分組，請問這裡的 random assignment 與 randomly selection 是否意義一樣?為什麼? (20%)

<div align="center">（試題請隨卷繳回）</div>