Mini Review

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RA Patients Who Attend Nurse-Led Rheumatology Clinics are the Subjects of a Randomised, Controlled Trial to Determine Their Outcomes and Cost Effectiveness

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Abstract

Background

The rise in the number of patients with arthritis coupled with understaffing of medical services has seen the deployment of Clinical Nurse Specialists in running nurse-led clinics alongside the rheumatologist clinics. There are no systematic reviews of nurse-led care effectiveness in rheumatoid arthritis. Few published RCTs exist and they have shown positive results for nurse-led care but they have several limitations and there has been no economic assessment of rheumatology nurse-led care in the UK.

Objective

This paper outlines the study protocol and methodology currently being used to evaluate the outcomes and cost effectiveness for patients attending rheumatology nurse-led clinics.

Design and methods

A multi-centred, pragmatic randomised controlled trial with a non-inferiority design; the null hypothesis being that of 'inferiority' of nurse-led clinics compared to physician-led clinics. The primary outcome is rheumatoid arthritis disease activity (measured by DAS28 score) and secondary outcomes are quality of life, self-efficacy, disability, psychological well-being, satisfaction, pain, fatigue and stiffness. Cost effectiveness will be measured using the EQ-5D, DAS28 and cost profile for each centre.

Power calculations

In this trial, a DAS28 change of 0.6 is considered to be the threshold for clinical distinction of 'inferiority'. A sample size of 180 participants (90 per treatment arm) is needed to reject the null hypothesis of 'inferiority', given 90% power. Primary analysis will focus on 2-sided 95% confidence interval evaluation of between-group differences in DAS28 change scores averaged over 4 equidistant follow up time points (13, 26, 39 and 52 weeks). Cost effectiveness will be evaluated assessing the joint parameterisation of costs and effects.

Results

The study started in July 2007 and the results are expected after July 2011.

Keywords: Nurse-led care • Clinical nurse specialists • Rheumatoid arthritis • Randomised controlled trial • Economic evaluation • Protocol

Introduction

Hepatitis A is an acute, usually self-limiting disease of the liver caused by hepatitis A virus (HAV). HAV is transmitted from person to

person, primarily by the fecal-oral route. The incidence of hepatitis A is closely related to socioeconomic development, and sero-epidemiological studies show that prevalence of anti-HAV antibodies in the general population varies from 15% to close to 100% in different parts of the world. In areas of low endemicity, hepatitis A usually occurs as single cases among persons in high-risk groups or as outbreaks involving a small number of persons. In areas of high endemicity, most people are infected with HAV without symptoms during childhood. In areas of low and intermediate endemicity, transmission occurs primarily from person to person in the general community, often with periodic outbreaks. In these countries, many individuals escape early childhood infection, but are exposed later in life, when clinical hepatitis occurs more frequently. In these areas, most cases occur in late childhood and early adulthood, and hepatitis A infection has more severe clinical progress and is the most common cause of liver transplantation. There are very limited data about the safety and immunogenicity of hepatitis A vaccine. Many doctors believe that vaccination increases the risk of relapse in rheumatologic diseases. As a result, vaccination in these patients shows significant variation and leads to insufficient immunization. In this study, we aimed to evaluate the immune response to hepatitis A vaccine and vaccine safety in children with JIA [1, 2].

Materials and Methods

Study design

This is a pragmatic trial in a complex clinical environment and is conducted over 4 years as a multi-centred RCT. Patients are randomised using an office hours remote secure telephone randomisation service provided by the Clinical Trials and Research Unit, University of Leeds. Patients who fulfil the eligibility criteria and have provided written informed consent are randomised on a 1:1 basis to either Nurse-led clinic (experimental group) or a rheumatologist-led clinic (control group). Randomisation is by random permuted blocks, using the stratification factors; centre and DAS28 score at baseline. After recruitment, patients have 5 follow-up visits over 12 months. The methods are consistent with current guidelines on design, conduct and analysis of pragmatic randomised clinical trials and those explicitly for non-inferiority trials [3].

Study population

The study comprises 180 patients with rheumatoid arthritis recruited from 10 rheumatology centres throughout the UK. Patients with both stable and active disease are included as this reflects the practice of clinical nurse specialists in the UK and Europe and so make the results more meaningful. All patients are seen in one of the 10 participating centres. The centres are distributed throughout the UK and this provides a socio-demographic mix of patients. Inclusion criteria are: a positive diagnosis of rheumatoid arthritis as defined by the American Rheumatism Association aged 18 years or above and ability to complete questionnaires unaided. Exclusion criteria are: patients unwilling to be randomised to a nurse-led clinic or rheumatologist-led clinic; patients suffering from unstabilised concomitant disease; patients awaiting surgery and patients who have already received care from the practitioners involved in the study [4].

Hypothesis

The hypothesis is that the outcomes from nurse-led clinics will not be inferior to those obtained by the rheumatologist-led clinics, but at a lower cost and greater patient satisfaction.

Interventions

Following randomisation, patients are given appointments with their respective practitioners for weeks 0, 13, 26, 39 and 52. When patients arrive at the clinic, they are seen by an independent assessor who oversees the completion of pain Visual Analogue Scale (VAS), fatigue VAS, the length of morning stiffness and performs joint counts for Disease Activity Score (DAS28). The independent assessor also gives the patient their blood form, questionnaires in a freepost return envelope and sends them to the waiting area ready to see their allocated practitioner. The joint examination for DAS28 can be prone to inter-observer variation and training or agreement sessions have been shown to minimise this. Therefore a training session was conducted (by MN) with the independent assessors at the study set-up meeting to ensure standardisation. The joint examination technique was based on the European League against Rheumatism handbook of clinical assessment in rheumatoid arthritis. Since this is a pragmatic trial, the practitioners in both arms of the trial (Clinical Nurse Specialists and the Rheumatologists) did not receive any more training; they manage their patients according to their normal practice [5].

Outcome Measures

Primary and secondary outcomes

The primary outcome measure is the DAS28 an internationally recognised measurement of disease activity in rheumatoid arthritis. It is a composite

measurement comprising objective (number of swollen joints and erythrocyte sedimentation rate [ESR] or C-reactive protein [CRP]) and subjective (number of tender joints and patients global assessment) indices [6]. DAS28 score has been shown to be a strong predictor of physical disability and radiological progression and a sensitive discriminator between patients with high and low disease activity. DAS28 score is widely used in making decisions about treatment effectiveness and it forms the basis for the European League against Rheumatism response criteria for rheumatoid arthritis. Scores can range from 0 to 9.4, assuming that an ESR of 100 is taken as the upper limit. Levels of disease activity are defined as DAS28 ≤3.2 mild; DAS28 >3.2 and ≤5.1 moderate; DAS28 >5.1 severe. The DAS28 will be measured at baseline and 13, 26, 39 and 52 weeks [7].

Discussion

Healthcare resource use, specifically in relation to rheumatoid arthritis, is derived through clinic audits and follow up patient questionnaires, and embraces health professional consultations (primary and secondary care), hospital admissions (day care, inpatient stays, A&E visits), investigations, and treatments including over-the-counter medications. Costs will be derived from sources of 'national average' costs, and also by direct elicitation from the self-report questionnaires for private out-of-pocket expenditure on health care service use, travel, medication, aids and special dietary requirements [8]. Data collected from each patient on employment status and job title (classified according to its socioeconomic classification using the Office of National Statistics (ONS) approach will be used to determine productivity losses using the human capital approach by multiplying a patient's reported number of days off work by the expected average daily wage extracted from National Statistics survey databases. Multiple imputations will be used to address missing cost data. Health outcomes will be assessed through QALYs derived from the EQ-5D for the cost utility analysis, and the DAS28 change score for the cost effectiveness analysis (with incremental differences in cost being evaluated in relation to the non-inferiority margin of 0.6 in mean DAS28 change). Between-group economic comparisons will focus on the joint estimation of incremental costs and effects [9, 10].

Acknowledgment

None

Conflict of Interest

None

References

1. Little PJ, Drennon KD, Tannock LR *et al*. Glucosamine inhibits the synthesis of glycosaminoglycan chains on vascular smooth muscle cell proteoglycans by depletion of ATP. *Arch Physiol Biochem*. 114, 120-126 (2008).
2. Tomlin JL, Sturgeon C, Pead MJ *et al*. Use of the bisphosphonate drug alendronate for palliative management of osteosarcoma in two dogs. *Vet Rec.* 147, 129-132 (2000).
3. Psychas V, Loukopoulos P, Polizopoulou ZS *et al*. Multilobular tumour of the caudal cranium causing severe cerebral and cerebellar compression in a dog. *J Vet Sci* 10, 81-83 (2009).
4. Loukopoulos P, Thornton JR, Robinson WF *et al*. Clinical and pathologic relevance of p53 index in canine osseous tumors. *Veterinary Pathology*. 40, 237-248 (2003).
5. Bech-Nielsen S, Haskins ME. Frequency of osteosarcoma among first-degree relatives of St Bernard dogs. *J Natl Cancer Inst*. 60, 349-353 (1978).
6. Wilkins RM, Cullen JW, Odom L *et al*. Superior survival in treatment of primary nonmetastatic pediatric osteosarcoma of the extremity. *Ann Surg Oncol.* 10, 498-507 (2003).
7. Kundu ZS Classification, imaging, biopsy and staging of osteosarcoma. *Indian J Orthop*. 48, 238-46 (2014).
8. Papalas JA, Balmer NN, Wallace C *et al*. Ossifying dermatofibroma with osteoclast-like giant cells, report of a case and literature review. *Am J Dermatopathol*. 31, 379-383 (2009).
9. Gelberg KH, Fitzgerald EF, Hwang SA *et al*. Fluoride exposure and childhood osteosarcoma, a case-control study. *Am J Public Health.* 85, 1678-1683 (1995).
10. Luetke A, Meyers PA, Lewis A *et al*. Osteosarcoma treatment where do we stand a state of the art review. *Cancer Treat Rev*. 40, 523-532 (2014).