

HealthWatch Prize (2008) for the critical appraisal of clinical trials protocols

Each of the following four pages contains a protocol for a hypothetical clinical trial. Read these protocols carefully, and rank them in order of quality - that is, **give the rating 1 in the box opposite the trial that you consider is most likely to provide a reliable answer to the stated aim of the trial, and 4 to that least likely to do so.**

Title of trial	Rating
(a) Emollients for dermatitis	[]
(b) Saffron for PMT	[]
(c) Breathing exercises for asthma	[]
(d) Glucosamine for knee pain	[]

On a single separate sheet of A4 paper type not more than 600 words to explain your reasons for assigning these ratings. This requires you **to identify flaws in design** of the protocols, so, if the trial was carried out, the conclusion could not be firmly established. If a protocol is fatally flawed say so; if it has minor remediable flaws indicate how it could be improved.

NB. You are assessing the quality of the protocol, not the desirability of the aim. Each protocol starts (as it should) with a "Scientific background" summarising previous relevant research. Entrants should assume this is work correctly cited from reliable sources.

Enter below your own particulars: do not put any identification on your typed sheet. Return this sheet and your typed sheet *before 31st July 2008* to

Dr Joan Gandy, PO Box 246, Pinner, Middx, HA5 3WD

Do not return the protocols. Your typed sheet and this sheet will be coded, and the typed sheet only will be sent to the judges who will be blind to your identity and training course.

Name and postal address:

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Telephone.....Mobile.....

Email.....

College and course on which you are registered

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Member of staff who can confirm that you are a registered undergraduate student

Name.....Email.....

Signature of entrant Date

How did you hear about this competition?

.....

(A) Do emollients improve treatment results with topical steroids in childhood atopic dermatitis? A clinical trial

Atopic dermatitis is a distressing condition which is common in childhood. When severe the lesions can become infected and unsightly. Sufferers are often very conscious of the lesions and may avoid social contact because of them. Steroid cream is the standard treatment but often very potent creams are required for clinical improvement. Concern has been expressed at the absorption of steroids through the damaged skin. It is claimed that emollients reduce the amount of steroid cream needed to control dermatitis.

Aim

To see if emollients improve the treatment results with steroids in atopic dermatitis

Methods

The volunteers will be recruited from the dermatology clinic of a large paediatric hospital. A specialist nurse, who has extensive knowledge of the management of atopic dermatitis and who has been trained in its assessment by the Eczema Area and Severity Index scale (EASI), will see all the volunteers.

Sixty children aged 4 - 10 years, who have suffered with severe eczema for at least two years, will be divided into two groups A and B. Those in group A will apply 1% steroid cream to the skin lesions once daily for two weeks. Those in group B will apply emollients twice daily and 1% steroid cream once daily to the lesions for two weeks.

The lesions will be assessed by the specialist nurse before treatment starts and then at day 7 and day 14 (end of treatment). At each visit, the nurse will calculate the EASI for each trial participant. One month after the trial has finished, the research nurse will telephone the children's mothers to ask how the atopic dermatitis has been since the creams were stopped.

Statistics

The EASI scales for the children in group A will be compared with those from group B. A decrease of two on the EASI scale is clinically significant. If group B has a larger reduction in the EASI score than group A it will show that emollients improve the treatment results of steroid in atopic dermatitis.

If the children's mothers report that, one month after the treatment has stopped, the dermatitis has been better in group B than group A it will prove that emollients reduce the amount of steroid required to control dermatitis.

(B) Saffron in the treatment of pre menstrual syndrome

Pre menstrual syndrome (PMS) is common. It affects at least 20% of women of reproductive age. It is cyclical, occurring in the luteal phase of the menstrual cycle and can cause severe mood and behavioural disorders. Saffron has been shown to be effective in the management of mild and moderate depression; it would be of interest to see if it also has a beneficial effect on PMS symptoms.

Aim

This study aims to determine if Saffron is effective in the management of PMS

Methods

One hundred women, aged 20 - 45 years, with PMS diagnosed according to RCOG criteria, will be recruited. Pregnant women, those with irregular menstrual cycles, a history of psychiatric disorder, or using psychoactive drugs/medication for PMS, will be excluded. Ethics committee approval and written informed consent will be obtained before study entry.

Women will be recruited by advertisement in the media. After a telephone consultation to check eligibility criteria, the women will attend for interview. All clinic visits will be scheduled for the pre-menstrual phase of the cycle. Those who agree to participate will keep a daily symptom record (a checklist of frequently reported PMS symptoms, rated from 0-4) and undergo psychiatric interviews to assess the Hamilton depression rating.

Following recruitment, the women will have a two-months running-in period, documenting their experience of PMS symptoms, to provide a baseline record. Thereafter, women will be randomised to saffron or identical looking placebo on a 1:1 ratio, using a computer generated code. Women will be seen pre trial, at the end of the two-months running-in period, and at 2, 4 and 6 months after the start of medication. At each visit, they will be assessed by a psychiatrist to determine their Hamilton rating, and the daily symptom records will be averaged for the pre- and post-menstrual phase of the cycle. Reasons for drop-out will be recorded. The women and all study-related personnel, including those responsible for data analysis, will be blinded.

On study conclusion, the effect of saffron and placebo will be measured by comparing the pre-treatment scores with those at 2, 4 and 6 months of treatment.

Statistics

The sample size was calculated to be 75, based on the pilot study; differences were considered significant at $p < 0.05$, the final difference between the two groups at least a score of 10 on the daily symptom report and power 0.8. Analysis will be by the two way repeated measures analysis of variance. Intention to treat analysis will be used.

(C) Do breathing exercises reduce the requirement for medication in asthma?

It has been claimed that deep breathing exercises, performed for 5 minutes a day, can help the symptoms of asthma and reduce the amount of “reliever” medication (usually Salbutamol) required to alleviate symptoms. This study was designed by the medical director of Eastside Primary Care Trust (PCT). It is hoped that by encouraging all asthmatics to perform regular breathing exercises a cost saving can be made on the prescription of Salbutamol.

Aim

To assess if breathing exercises are helpful in the management asthma.

Methods

Ten GP practices will take part in the study. There are guidelines for the management of asthma in Eastside PCT. They state that all asthmatics should have an annual review with a specialist nurse. If a patient defaults from the annual review, the GP should not issue any further repeat prescriptions.

All patients with asthma requiring daily inhaled steroids are eligible for inclusion in this study. Those who require oral steroids, nebulisers or oxygen will be excluded.

At their annual review, the specialist nurse will describe the breathing exercise to the patients and ask if they wish to volunteer for the study.

Those who volunteer to perform the exercise daily will be asked to measure their peak flow twice daily and to monitor their Salbutamol requirement over the following three months. They will be asked to make an appointment in three months time. At this visit, the nurse will calculate their average weekly peak flow and calculate the use of reliever medication in each month.

Those patients who do not want to perform regular breathing exercises will be asked to measure their peak flow twice daily. They will be phoned by the nurse three months after their review to ask how much Salbutamol they have used in the past month, and their average peak flow over the last four weeks will be calculated.

Statistics

At the end of the study, the amount of Salbutamol being used by the volunteers who performed the exercises will be compared to that used by those not performing exercises. If those performing regular exercise have used less Salbutamol, it will prove that breathing exercises help in the relief of asthma

(D) Glucosamine for knee pain caused by osteoarthritis

Knee pain is very common in the middle aged and elderly. One of the commonest causes of knee pain is osteoarthritis. It is well known that analgesics, anti inflammatories and knee exercises can relieve pain and improve function. There are significant side effects from long term analgesic consumption. Many patients have difficulty performing knee exercises regularly. Glucosamine is said to relieve pain caused by osteoarthritis. If true, regular glucosamine would reduce the amount of analgesics consumed by people with osteoarthritis.

Aim

This study aims to determine whether regular consumption of glucosamine reduces the level of pain in osteoarthritis of the knee.

Methods

Volunteers will be recruited from the Rheumatology clinic. Exclusion criteria include history of rheumatoid arthritis, history of joint injections and a history of surgery. All volunteers will have had a knee X ray which demonstrated radiological changes compatible with osteoarthritis. Pain will be assessed by the WOMAC visual analogue and mobility score.

One hundred volunteers will be randomly allocated to either glucosamine or placebo. One tablet will be taken daily for the three month study period. Each volunteer will be seen prior to the study and then monthly by a research nurse. At each visit, the WOMAC score for the preceding month will be calculated and an enquiry made as to whether any additional pain killers have been taken. Neither the volunteers nor the research nurse will know which tablets a given patient is taking.

Statistics

A change from baseline of 10 points in the WOMAC score is considered clinically significant. A previous pilot study has suggested that 100 volunteers are required to detect this difference with a two sided error of 5%.

At the end of the study the randomisation code will be broken and the data analysed using a paired Student's T test on intent to treat basis.