

HealthWatch Prize (2004)

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
HINBUV for civilian shrapnel injuries (<i>HINBUV</i>)	[]
Hypnosis for osteoarthritis of knee (<i>Hypnosis</i>)	[]
Herbal treatment for menopausal symptoms (<i>Herbal</i>)	[]
Zinc supplementation and middle ear infection (<i>Zinc</i>)	[]

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 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 2004 to
Dr Joan Gandy, PO Box 246, Pinner, Middx, HA5 3WD

Do not return the protocols. Your typed sheet and this sheet will be assigned code numbers, 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.....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

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Signature of entrant Date

How did you find our about this prize competition?

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HINBUV for civilian shrapnel injuries

Scientific background

Car bombs cause relatively minor injuries to a very large number of civilians, especially puncture wounds from shrapnel and glass fragments. These carry bacteria from skin and clothing into the tissues. In dry dusty conditions (eg. Middle East) serious infections of these wounds by anaerobic bacteria are common, and difficult to treat with antibiotics. A formal surgical cleaning of every wound is impractical when there are up to 100 casualties to be treated at once, and routine use of broad-spectrum antibiotics promotes the development of resistant strains of bacteria.

Recent unpublished military research has shown that a High Intensity Narrow Band Ultra-Violet (HINBUV) lamp directed at a puncture wound for 15 seconds will kill all pathogenic organisms (including anaerobes) over an area of 10 x 10 cm, and to a depth of 4 cm, without damaging normal tissue. The area of skin treated then has a characteristic grey tinge that lasts for 3 - 4 weeks, by which time the wound has healed. The treatment is not used for facial injuries, since it may damage the retina of the eye.

Aim of the investigation

To test the ability of HINBUV lamps to provide, in dusty conditions, more rapid and effective treatment of civilian shrapnel injuries than conventional surgical dressing combined with broad-spectrum antibiotics.

Method

At each military hospital one field ambulance will be equipped with a HINBUV lamp with crew trained in its use, but will not have any external marking to indicate that it has this equipment. All other ambulances at that hospital will continue to use conventional equipment when called to a car-bomb incident. Casualties at the bomb site will be assigned to the ambulances as they become available. Cases allocated to the HINBUV unit will be treated on site with the lamp, and the wound covered with an appropriate surgical plaster. No antibiotics will be administered. Cases allocated to other ambulances will be transported to the hospital for conventional treatment. The number of cases treated by each method will be logged. After treatment the casualty will be given a voucher entitling him/her to visit the military hospital one week later for a check-up and to have the dressing changed.

Analysis and interpretation

The proportion of cases treated by each method who report for check-up one week later, and the healing of the wounds, will be compared. The superiority of the HINBUV lamp method will be established if (a) more casualties per incident are treated by this method, (b) wound healing at 1 week is better than the control group. Prevalence of antibiotic resistance will be monitored but any decrease cannot be ascribed specifically to the HINBUV treatment.

Hypnosis for osteoarthritis of knee

Scientific background

Osteoarthritis (OA) of hips and knees is the commonest disabling condition in people over the age of 60 years. The characteristic radiological appearance of narrowing of the joint space in the knees reflects irreversible destruction of joint cartilage, and there is also inflammation in the surrounding soft tissues. Analgesics, anti-inflammatory drugs and gentle exercise relieve pain and improve joint function, but there are significant side effects from long-term drug treatment. It would therefore be very valuable if control of symptoms could be achieved by adding hypnotherapy and reducing drug dosage.

Aim of the investigation

To test the hypothesis that a combination of drug treatment and hypnosis would achieve control of symptoms in OA of the knee that had previously required a higher dosage of drugs.

Methods

Participants will be recruited from residents at old people's homes where there are 73 people with OA of the knees and symptoms controlled on a stable dosage of drugs. From this population we will seek informed consent from 20 residents to accept hypnotherapy and a reduced drug dosage, and select a control group of 20 residents matched for age, sex and severity of OA, who will maintain their usual drug regimen. The pain and disability of all the participants will be assessed by a visiting consultant rheumatologist at the beginning of the study, and again after 6 weeks of treatment. The Ethics Committee of the Primary Care Trust has approved this protocol. After the baseline examination the hypnosis group will have 30 minute hypnosis sessions twice a week, reinforcing self-control and tolerance of pain. After the first week the drug dosage will be gradually reduced at the discretion of the patient until this is limited by increase in pain.

Analysis and interpretation

If, after 6 weeks of treatment with hypnosis, the dosage of drugs has been reduced, and the pain and disability (assessed by the rheumatologist) has not increased, it will show that the addition of hypnosis has made it possible to control the symptoms of OA of the knee with a reduced dosage of drugs.

Herbal treatment for menopausal symptoms

Scientific background.

Frequently reported menopausal symptoms are hot flushes, night sweats, vaginal dryness, loss of libido, depression and poor concentration/forgetfulness. The conventional treatment is hormone replacement therapy (HRT) which usually relieves these symptoms, and has the added benefit of reducing the risk of osteoporosis. However recently there have been warnings that long-term HRT increases the risk of breast cancer or hypertension. Alternative treatment is by medicinal herbs that have oestrogen-like properties.

Aim of the investigation

To compare the efficacy in relieving menopausal symptoms, over 24 weeks, of tablets containing two plant sources of oestrogen (black cohosh and soy) or placebo tablets.

Method

Participants in the trial will be recruited at specialist clinics at District Hospitals in Yorkshire, Northumberland and Cumbria. Criteria for entry are that the women are aged 45-55 years, have ceased menstruating, and suffered from hot flushes and at least two other of the five symptoms of menopause listed above. Women meeting these criteria will have measurement of oestradiol, LH and FSH to confirm the diagnosis. Signed consent will be obtained from volunteers that they understand and accept the randomised placebo-controlled trial design. Recruitment will cease when a total of 200 women have been enrolled at the three participating centres. After a 4-week observation period to establish baseline symptoms, participants will be randomly assigned to two tablets per day of either the plant oestrogen mixture, or placebo tablets identical in appearance and packaging. Severity of symptoms (on a scale of 0-10) experienced during the preceding 4 weeks, will be recorded at baseline and every 4 weeks. Participants will be asked at week 8 and week 24 if they can guess whether they are on the plant oestrogen or placebo tablets. Concurrent medication and reasons for dropout will be recorded.

Analysis and interpretation

For each participant the average severity of each symptom (up to a maximum of 6 symptoms) at week 8, 12, 16, 20 and 24 will be expressed as a percentage of the severity at week 4. Dropouts before week 8 will be excluded from analysis but, for those who drop out between week 8 and 24, the symptom scores up to the last attendance will be analysed. The average change in severity score for each symptom after week 4 will be compared between those on plant oestrogen, and those on placebo.

If the guessed allocation at week 8 and 24 was not significantly ($p < 0.05$) associated with the correct treatment group, this shows the blinding of participants to allocation was effective. If the group on plant oestrogen record a significantly ($p < 0.05$) greater reduction in symptom score than the placebo group this shows that these plant oestrogens over 20 weeks are better than placebo at relieving menopausal symptoms.

Zinc supplementation and middle ear infection in Indian children

Scientific background

Zinc deficiency is common in malnourished young children in Central India, and Zn supplementation of the diet has been shown to decrease the prevalence of some infections in these children. Nutritional supplements to a rural community with about 3000 children in the age group 1-3 years are provided by a local health centre, at which 10-15 children per week attend with recurrent middle ear infection. Typically a child, after treatment with an antibiotic on the first visit, will return 2-6 times over the next 4 months with a new middle ear infection.

Aim of the investigation

To see if the re-infection rate is reduced in undernourished children given 20 mg Zn daily for 4 months, compared with those given a placebo.

Methods

Malnourished children attending the centre are routinely given a general nutritional supplement providing protein and a multivitamin mixture recommended by WHO, but this mixture does not contain zinc. With the consent of the mother, children with ear infections will be given additionally a plastic bottle containing syrup that will provide 20 mg Zn (as zinc gluconate) daily for a month, or a placebo syrup with the same appearance and taste. Packs of four bottles with either Zn or placebo syrup are shipped from the Institute of Medical Sciences (IMS) in Delhi. All four bottles in a pack bear the same serial number, which is entered in the child's record card at the centre, so bottles from the same batch can be given on the return monthly visits over the next four months. The code linking the serial number to the Zn content of the syrup is determined by a random sequence held at IMS, so both the healthcare workers in the centre and the recipients are blind to the allocation. In addition, the syrup of both types has a tracer amount of lithium chloride that can be detected by testing the child's urine with a dipstick: a negative result indicates that the child has not been taking the prescribed dose of syrup.

At each return visit the child is examined for signs of ear infection (and other infections), the urine is tested for lithium tracer, these results are entered on the record card, and the mother is given another bottle from the same pack. At the final visit after 4 months the record card is completed and returned to the IMS.

Analysis and interpretation

At IMS the cards are processed to determine if there are fewer infections in the Zn supplemented children, and if there is a significant difference ($p < 0.05$) between the records of Zn supplemented and placebo children in compliance as indicated by the lithium tracer.