Registered Charity No 1003392

2018 Protocol A

Acupuncture for the prevention of tension headache

Scientific background

Traditional acupuncture is based on the belief that an energy, or "life force", flows through the body in channels called meridians. This life force is known as Qi (pronounced "chee"). Practitioners who adhere to traditional beliefs about acupuncture believe that when Qi doesn't flow freely through the body, this can cause illness. They also believe acupuncture can restore the flow of Qi, and so restore health. There is some preliminary evidence that acupuncture might reduce the frequency of tension-headache.

A tension-type headache is the most common type of headache and the one thought of as a normal, everyday headache. It may feel like a constant ache that affects both sides of the head. One may also feel the neck muscles tighten and a feeling of pressure behind the eyes. A tension headache normally won't be severe enough to prevent everyday activities. It usually lasts for 30 minutes to several hours, but can last for several days.

Aim

This study aims to demonstrate that a course of acupuncture will reduce the frequency and/or severity of tension headache.

Methods

25 patients presenting to one of 5 collaborating acupuncture centres with a complaint of tension headache will invited to join the trial. They will be told that the study compares two types of acupuncture and lasts 12 weeks but they will only be charged for 6 weeks. They will be allocated to two types of treatment in random order decided by the toss of a coin, but will not be told in which order the treatments will be given. Both treatments involve a course of six 15-minute sessions spread over 6 weeks. Treatment A will use the meridian points indicated for this condition, and treatment B will use other meridian points associated with abdominal pain. (Patients will therefore be charged for only for the treatment A period.) Patients will keep a weekly diary of the occurrence, duration (hours) and severity (mild, moderate or severe) of episodes of headache, and return it at each visit. Patients on anticoagulant treatment will be excluded, as will any who are acupuncture therapist (as they will recognise the treatment meridians).

Analysis

The sum of the duration multiplied by severity of the headaches will be calculated for each patient for each treatment period. As a paired t-test can be used for statistical significance the study will be able to detect even a small difference, so if this is lower for the treatment A period this will achieve the aim of the study. However, in case practice technique differs between centres and not all practitioners achieve the benefit, this calculation will also be done for each centre separately.

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2018 Protocol B

Castor oil to treat baldness

Scientific Background

It has long been known that castor oil is one of the natural cures for baldness and works as a humectants (a substance that absorbs or helps another substance retain moisture). All that is required is to pour some castor oil in the palm of the hand and gently massage it on the bald areas of the head. This will help in nourishing the hair and boost hair growth.

Aim

This project is designed to demonstrate that regular use of castor oil improves hair growth.

Methods

Many people seek help for their problems with baldness by consulting at our natural remedies clinic. We will use our web site to invite men between the ages of 25 and 45 (a time when men are particularly concerned about their appearance) to volunteer to join the study, and will offer a 50% treatment discount if they do so.

Participants will be offered our own superior brand of specially prepared castor oil to apply to the balding areas each evening for 2 weeks, and a standard commercially available shampoo to use each day for 2 weeks as a comparison. The products will be mailed to the participants and in order to prevent any bias, the order in which these are to be used will be randomised.

At the end of each 2 week period participants will complete our on-line questionnaire, which asks about their worries and concerns about hair loss, how they feel about it now, and whether they think hair growth has improved over the previous 2 weeks.

Participants will also answer the questions, “Which two week period was best for your hair?” and “Would you recommend our superior brand of specially prepared castor oil to others?”

Analysis

To reduce the time taken to complete the study we will keep a continuous track of the responses of study participants. The chance of random selection of the castor oil as the preferred treatment is less than 5% for 5 people in a row (25=1 in 32 or 3.13%) and so we will stop the study when 5 people in a row have chosen castor oil.

Registered Charity No 1003392

2018 Protocol C

Low-dose sulfasalazine to prevent relapses of Graves' hyperthyroidism

Background

Grave's disease (autoimmune hyperthyroidism) is often treated with the antithyroid drugs carbimazole or PTU (propylthiouracil). Unfortunately, even after a full course of treatment lasting twelve to eighteen months it is common for the disease to relapse once treatment has been withdrawn.

Aim of the study

The study will investigate whether treatment with low-dose sulfasalazine for two years after the end of a course of antithyroid drugs will reduce the frequency of relapses in patients with Graves' hyperthyroidism.

Method

The investigators will seek research ethics committee approval for the study. Patients will be recruited from endocrine out-patient clinics in the south-east of England. The diagnosis of Graves' hyperthyroidism will be confirmed clinically and by measurement of thyroid hormone levels. Patients will be considered for entry into the trial if they are aged 18 to 70 years and are not pregnant or breastfeeding. Subjects with large goitres, thought to require surgery for mechanical reasons, will be excluded. The nature of the trial will be explained to suitable subjects, who will then be randomised to receive either sulfasalazine, 250mg once daily or identical placebo tablets; randomisation will be by the use of a computer-generated code. Neither the participants in the trial nor the investigators will be informed as to the group to which any individual has been allocated.

Follow-up

At the end of each participant's course of antithyroid drugs s/he will commence the allocated trial drug or placebo which s/he will take for two years. Each participant will be seen every two months in a special trial clinic where s/he will complete a symptom questionnaire (symptoms of hyperthyroidism being scored using a Likert scale) and will have blood taken for the measurement of thyroid hormones. A relapse of the patient's hyperthyroidism will be deemed to have occurred if either the serum level of tri-iodothyronine (T3) is found to be more than 10 per cent above the upper limit of the reference range and the patient has symptoms of hyperthyroidism or if the serum level of T3 is more than 20 per cent above the upper limit of the reference range, whether or not s/he has symptoms.

Analysis

Results will be analysed on an intention-to-treat basis. Symptom scores and thyroid hormone levels will be compared using appropriate statistical tests. The primary end point will be the percentage of the active treatment group and of the placebo group who relapse into hyperthyroidism during the two-year study period.

Registered Charity No 1003392

2018 Protocol D

Saffron in the treatment of pre-menstrual syndrome

Scientific background

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 record of their menstrual periods, 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 phases of the cycle. Compliance will be checked by means of tablet-count, and 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.