Registered Charity No 1003392

2021 HealthWatch student prize competition for critical evaluation of clinical research protocols

Your entry must be submitted before 23:59 BST on Friday 30 April 2021. Entries received after that time will not be considered.

The competition is open to all full-time undergraduate students of medicine, dentistry, nursing, midwifery and professions allied to medicine, and post-graduate students taking a taught master's course in any of those subjects. Post-graduate research students are not eligible to enter. Entries are welcome from eligible students in any country. Students in their final year of study are also eligible to enter.

Entries are judged in two classes: students of medicine and dentistry, and students of nursing, midwifery and professions allied to medicine. There is a first prize of £500 and up to five runner-up prizes of £100 in each class.

The competition consists of four hypothetical research protocols to be evaluated and critiqued. In devising the protocols, the judges have worked with a checklist of the various features that a good research protocol should include, and have ranked them in order according to how many of these features are included.

Your first task is to rank the protocols, and the first stage of judging your entries is to compare your ranking of the protocols (in order of quality from best to worst) with this predetermined ranking. All entrants who have the correct ranking will receive a certificate of merit when the results are announced, and all will be assessed in the second stage of judging.

Your second task is to explain, in no more than 600 words altogether, your reasons for the ranking you have given, discussing each protocol in a separate paragraph. You should imagine that you are a member of a research funding body, and explain why you would award a grant to the protocol that you rank first, as well as explaining the strengths and weaknesses of each of the protocols. If a protocol is fatally flawed say so; if there are minor flaws, indicate how they could be improved. There is no need to comment on, or analyse, the statistical methods that are proposed. You are assessing the methodological quality of the protocol, not the desirability of the aim. Each protocol starts (as it should) with a 'scientific background' summarising previous relevant research. You should assume this is work correctly cited from reliable sources.

Entries will first be assessed for the number of the key criteria of a good research protocol that you mention as being present or absent in each of the protocols. The protocols are each marked out of 10, and in order to be eligible for a prize you must achieve a score of 28 (70%) or more. For all entries reaching this threshold the judges will then consider your arguments and critique of the protocols to determine the prize winners. Prize winners will be invited to the HealthWatch Annual General Meeting in London in October to receive their prizes. Travelling

expenses at student travel rates will be reimbursed; for entrants outside the UK up to £100 will be allowed for travel expenses. Entrants who cannot attend the AGM will have their certificates and cheques sent by post. If, for any reason, large gatherings or travel are restricted the AGM may be held virtually, in which case prize-winners will be invited to attend remotely.

Submission of entries is via the HealthWatch website, and all entries are forwarded automatically to the student prize coordinator, who undertakes the first stage of judging – sorting those entries that have given the predetermined correct ranking. All entries that qualify are then forwarded to the judges with no indication of the name of the entrant. All entrants will be invited to join HealthWatch as student members, who pay no subscription, and in the summer of their graduation will be invited to continue their free membership for a further two years.

You have three months between the launch of the competition and the deadline for submission of entries; do not leave your entry until the last minute. Entries submitted after midnight on the day of the deadline will not be accepted, and no extension to the deadline can be allowed for any reason.

The judges' decision is final, and no correspondence can be entered into.

The protocols are given below:

Protocol A: Bracelets for transdermal menopausal hormone therapy

Protocol B: Chloroquine and dexamethasone for the common cold

Protocol C: Mefenamic acid for Pain Control in IUD (Intra-Uterine Device) Fittings

Protocol D: Raspberry leaf for use in pregnancy

We are grateful to the Royal College of Surgeons of England for their sponsorship of this year's competition.

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Protocol A

Bracelets for transdermal menopausal hormone therapy

Scientific background

In addition to sleep disorders, low mood and other identifiable symptoms associated with menopause, the increased risk of developing diabetes mellitus and dementia attributable to a reduction in the secretion of regulatory hormones oestrogen and progesterone has led to significant advancements in menopausal hormone therapy (MHT). The common routes of administration have been oral, subcutaneous, and vaginal. However, in recent times, the transdermal route, involving the use of patches, is becoming more popular due to its ease of use and bypass of the first pass effect.

Aim

To assess the efficacy of a close-fitting, medicated bracelet in the transdermal administration of MHT (a combination of an oestrogen and a progestagen).

Method

This is a randomised double blind, double dummy, equivalence comparative study comparing standard transdermal patches to a close-fitting medicated bracelet (both of which are renewed weekly). Women will wear patches and bracelet simultaneously for 6 months. For 3 months the patches will be placebo, and for 3 months the bracelet will be placebo. These periods will be randomly allocated in a sequence unknown to the trial team or the participant.

Women over the age of 50 attending a women's sexual health clinic and who have no contra-indications and are prescribed transdermal Menopausal Hormone Therapy by their therapist will be invited to consider enrolling in the study. The use of the bracelet and the nature of the study will be explained by a team member, and an information leaflet about the study provided.

After completing a consent form, participants will be provided with a three-month supply of patches and bracelets and a menopause symptom checklist, to be completed each week. This will also include a record of any discomfort from the device. Monthly telephone calls will encourage adherence with the protocol. At a clinic visit at 3 months the participant will be interviewed according to a schedule, the checklists collected, and the second three-month supply of patches, bracelets and checklist issued. At a clinic visit at 6 months the participant will be interviewed according to a schedule and the checklists collected.

We think about 100 participants should be a good target for recruitment, which will take up to one year.

Analysis

Standardised symptom checklist scores will be compared between treatments for the primary outcome. A secondary outcome will be discomfort.

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Protocol B

Chloroquine and dexamethasone for the common cold

Scientific Background

The COVID-19 pandemic has reinvigorated the search for effective treatment of upper respiratory tract viruses. The common cold is caused by the rhinovirus, a type of picornavirus, and it is responsible for upper respiratory tract symptoms that can last for up to ten days. Therefore, any drug that reduces symptom duration has the potential to reduce productivity losses due to viral upper respiratory tract illnesses by hundreds of millions of pounds per year in the UK alone.

Aim of Investigation

To compare the effectiveness of chloroquine against dexamethasone in the management of symptoms from the common cold.

Methods

Patients who present with or contact their GP regarding coryzal symptoms will be included in this study. This is a multi-centre study, involving 20 GP practices who, on the basis of prior research and our power calculations, will each be asked to recruit 150 patients (50 each per treatment arm (chloroquine and dexamethasone) and 50 in the control arm). Patients will be included if they are of working age (18-65) and normal BMI (20-25 kg.m2). Patients will not be invited to take part if they have asthma, COPD, or an admission to hospital for any respiratory tract infection in the previous 12 months.

This is an open label, randomised study with two treatment arms and a control arm. Treatment arm 1 chloroquine loading dose of 1000mg PO daily for 3 days followed by 600mg PO once daily to complete a two-week course in total. Treatment arm 2 consists of dexamethasone 4mg PO daily for 7 days. The control arm consists of usual care (advice on self-management of symptoms, patients are not offered any pharmaceutical interventions).

Patients will be invited to complete a survey at the start and end of their symptom period. The outcome measure is the time to self-reported end of symptoms.

Analysis and Interpretation

Time from onset to resolution of symptoms will be used to determine effectiveness of the two treatment modalities as this is the most economically relevant measure of outcome.

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Protocol C

Mefenamic acid for Pain Control in IUD (Intra-Uterine Device) Fittings

Scientific Background

Although approximately 50 % of women experience little or no pain during the insertion of an intrauterine contraceptive device, it can be painful for some women, especially if nulliparous. Various strategies to alleviate IUD insertion-related pain have been explored, including non-steroidal anti-inflammatory drugs (NSAIDs), local cervical anaesthetics, para-cervical block and cervical ripening agents. These are usually administered at the time of or after IUD insertion, and have shown varying degrees of success. It would be of interest to determine if NSAIDs given in advance of IUD fitting would be of help.

Aim

To determine whether the administration of mefenamic acid prior to IUD insertion alleviates insertion-related, and/or immediate post-insertion, pain.

Method

Following Research Ethics Committee approval, and distribution of written information about the trial via specialist clinics and GPs, healthy women requesting their first ever IUD will be referred-to and recruited at a large Women's Health Clinic in Central London. To be eligible, women have to be age 18 and over and free from the usual contraindications to IUDs and mefenamic acid (including past or current pelvic infection, acute cervicitis, and gynaecological abnormalities such as fibroids distorting the uterine cavity). Nulliparous and parous women will be eligible to join. Previous research suggested that 200 participants will be required. At the pre-insertion visit, women will receive further details about the trial, have their eligibility checked, their written consent obtained, and undergo a gynaecological examination. They will be taught how to complete visual analogue scales (VAS) for documenting the degree of pain experienced, where 0 indicates no pain at all and 10 the worst pain imaginable.

On the day of IUD fitting, patients will be seen 1 hour prior to the procedure by a research nurse, who will issue the patient with a trial number, and after opening a corresponding envelope that contains the assignment code chosen at random by computer-generated randomisation charts, administer 500 mg of mefenamic acid or a placebo. Both the trial medication and the placebo will be presented in identical-looking single-product containers, to maintain blinding. All IUD fittings will be carried out in the first 10 days of the menstrual cycle by one of four doctors, highly experienced in this speciality, using a standard Copper-IUD (TCu 380S), a standard insertion procedure, and a tenaculum forceps for stabilizing the uterus. Patients will complete VAS scores prior to IUD insertion (to indicate their anticipated degree of pain), immediately after the IUD is inserted, and at 1 minute and 10 minutes thereafter.

In addition, the doctors will complete a VAS, to indicate their perception of the degree of pain experienced by the patient during the IUD insertion. Further analgesics, if required, will be recorded as will insertion-linked adverse events e.g. vaso-vagal reaction.

Analysis and Interpretation

The VAS scores for the mefenamic acid group, documented at each of the time points specified above, will be compared with those in the placebo group and the differences tested for statistical significance. In addition, the VAS value recorded at the time of insertion will also be compared with that recorded pre-insertion.

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Protocol D

Raspberry leaf for use in pregnancy

Scientific Background

Raspberry leaf (rubus idaecus) extract is said to have beneficial effects in pregnancy and labour by toning uterine muscle due to its active constituent, the phytochemical fragarine. It may thus shorten labour and reduce the need for medical or surgical intervention during labour/delivery. It is recommended by doctors, midwives, and herbalists in pregnancy-related publications, on websites, and in clinical practice in Australia. However, its claimed efficacy is based largely on popular belief and anecdotal reports, rather than on sound research data. In view of this, we decided to undertake a clinical study to gain more evidence for its benefit during labour.

Aim

To determine if raspberry leaf extract shortens labour and makes labour 'easier'.

Method

The study will be publicised by means of information leaflets at local GP Practices and two large teaching hospitals in Central England. Volunteers must be aged 18 to 40 years, currently pregnant with a singleton pregnancy, willing to complete a follow-up questionnaire after delivery, and agree to have their hospital records inspected for pregnancy outcome.

Following a pre-enrolment telephone interview by the investigator to explain the study in more detail, check eligibility, and obtain her verbal consent, the woman will be sent a supply of raspberry leaf tablets (1.2 g per tablet) and advised to take two tablets per day, starting from 32 weeks gestation and continuing until the onset of labour. Further supplies will be posted to her as required.

After delivery, the woman will be sent a questionnaire for completion, asking about: the duration of labour; the date, type and quality of delivery (e.g. forceps delivery or caesarean section); and the type of analgesia used, if any (e.g. oral, epidural). Other questions will relate to: whether the trial medication was taken regularly; whether the duration of labour was as she had expected, or longer/shorter; whether she would consider the overall experience of labour to have been 'easy', 'acceptable' or 'difficult'; and whether she would use raspberry leaf extract in possible future pregnancies. The investigator will then inspect the woman's hospital records to verify the outcome of her pregnancy and delivery-related information.

Analysis and Interpretation

The women's responses to questions relating to the duration, and the overall quality of labour will be analysed, and if the majority women reported satisfaction, it demonstrates that raspberry leaf extract can make a positive contribution to women's child-bearing experience.