2022 HealthSense student prize competition for critical evaluation of clinical research protocols

Your entry must be submitted before 23:59 BST on Saturday 30 April 2022. 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 HealthSense 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 HealthSense 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 HealthSense 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: Cervical Membrane Sweeping: a non-pharmaceutical approach to the induction of labour at term

Protocol B: Health benefits of cupro-zinc insoles

Protocol C: Moxibustion for breech presentation

Protocol D: A new drug formulation for pulmonary embolism

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

Protocol A

Cervical Membrane Sweeping: a non-pharmaceutical approach to the induction of labour at term

Scientific Background

In a Cochrane review [1] of membrane sweeping as a way of inducing labour in women who are at or near term, and how it compared to formal methods of induction, the certainty of evidence (40 studies, 6548 women) supporting membrane sweeping was low. As women generally reported a positive feeling towards membrane sweeping, it is important to improve the quality of the research and to determine the ideal timing of the sweep as well as whether repeat sweeps are more effective than a single sweep.

Aim of Investigation

To determine the ideal timing of cervical sweep for the induction of labour.

Methods

Expectant mothers due to receive routine care will receive information about the trial at their booking appointment and will be invited to participate in the study at 36 weeks, when consent will be gained. Depending on their allocation, low risk women will receive either a single sweep or sham sweep (vaginal examination without cervical sweep) from 37 weeks onwards. All women will then continue to receive usual care, including pharmacological inducement of labour for prolonged pregnancy (between 40+7 and 40+12 weeks) but will receive no further membrane sweeps.

This is a multi-centre study involving 6 maternity units in NHS Foundation Trust Hospitals and is a single-blinded, randomised study. Each unit will aim to recruit 200 women (see Table 1) for a total of 1200 study subjects. Inclusion criteria include healthy woman under midwife led care, singleton pregnancy, cephalic presentation (fixed in pelvis), intact membranes, and placenta clear of the os. Exclusion criteria include suspicion of vaginal or uterine infection.

This protocol has been assessed and agreed by the Local Research Ethics Committees of the hospitals taking part in this study.

Continued over

Analysis and Interpretation

The following endpoints will be assessed:

1. Duration of pregnancy until established labour
2. Duration of pregnancy until delivery
3. Time from sweep to established labour
4. Time from sweep until delivery
5. Whether pharmacological induction or augmentation was required
6. Mode of birth (spontaneous vaginal delivery, instrumental delivery, surgical delivery)

Data will be analysed in an intention-to-treat analysis and therefore compliance does not require direct observation. However, investigators will be required to record why the decision to deviate from treatment protocol was made to inform future research.

Table 1. *Allocation of study participants to intervention and control arms*

Gestation at Time of Sweep	Cervical Sweep Group	Sham Sweep Group
37/40	150	150
38/40	150	150
39/40	150	150
40/40	150	150

References

1 Finucane EM, Murphy DJ, Biesty LM, Gyte GML, Cotter AM, Ryan EM, Boulvain M, Devane D. Membrane sweeping for induction of labour. Cochrane Database of Systematic Reviews 2020, Issue 2. Art. No.: CD000451. DOI: 10.1002/14651858.CD000451.pub3

Protocol B

Health benefits of cupro-zinc insoles

Background

Copper is one of the most important elements in the human body and worldwide studies have shown that a deficiency may cause rheumatic aches and pains, as well as other health problems. Cupro-Zn insoles are made from high-grade, purified copper and zinc and by wearing them, copper can be absorbed through the skin and circulated throughout the body; even when a person is wearing socks or hosiery. In addition, zinc is widely known to be a crucial part of a healthy immune system and deficiency of zinc is a recognised cause of impaired immunity.

Aim

To document the health benefits of wearing cupro-zinc custom-fitted insoles.

Methods

Patients attending a large group practice in Manchester will be invited to watch a short video about cupro-zinc insoles while waiting in the surgery waiting room. They will then be approached by a representative of Cupro-Zn plc and will be offered a chance to try the insoles for four weeks. Those patients who accept the offer will have their feet measured and will be supplied with two pairs of custom-fitted cupro-zinc insoles. They will be invited to return to the surgery after four weeks, where they will be interviewed by the same Cupro-Zn representative who will use the techniques of qualitative research and will ask them to complete a questionnaire describing their experiences with the insoles.

Analysis

The results of the questionnaires will be analysed according to whether the benefits reported relate to rheumatic-type symptoms alone or to improvements in general health such as energy levels, mood, etc. Results will be expressed as a percentage of respondents.

Protocol C

Moxibustion for breech presentation

Scientific Background

Breech presentation (head up) is common in the mid trimester of pregnancy. Women with a breech presentation at 36 weeks, are frequently offered External Cephalic Version (ECV). This is successful in 30 – 80 % of cases. ECV is not suitable for all, hence treatments that facilitate spontaneous version are being explored. These include moxibustion, a type of acupuncture that involves the application of heat to specific acupuncture points, by the burning of specific herbs (moxa). If moxibustion can be shown to be effective, women would avoid the need for Caesarean Section.

Aim

To determine whether moxibustion is effective in producing spontaneous version of breech presentation in late pregnancy.

Method

The trial will take place at five London hospitals after ethics committee approval was granted. Healthy women with a singleton pregnancy attending ante-natal clinics, who are found to have a breech presentation on physical examination by a midwife or obstetrician at 34–35 weeks gestation, will be invited to take part. They will receive verbal and written information about the aim and study procedures. Exclusion criteria include pelvic abnormalities; previous uterine surgery; foetal or uterine abnormality or other pregnancy complications.

Women who consent to take part, will be assigned to receive moxibustion or observation only, the group allocation being determined by computer-generated random numbers, held by a staff member not involved in the study. Recruitment will cease after a total of 250 women are enrolled.

Midwives, trained in the administration of moxibustion, will perform the first treatment. This involves burning sticks of the herb *Artemisia vulgaris* next to the acupuncture point BL 67 (tip of the fifth toe), to induce a warming sensation. Participants will then be taught the technique and advised to carry it out at home for 30 minutes (15 minutes per side) twice a day for seven days. All participants will complete a foetal movement (FM) count form twice a day for seven days, with the number of foetal movements counted in one hour. If, after one week of treatment (or observation-only) breech presentation persists (demonstrated on physical examination), the same treatment is to be continued for another week, and the patients will be examined again. Thereafter, all women who still have a breech presentation, will be offered ECV.

Primary outcome measure is the number of spontaneous versions after two weeks of treatment; secondary end-points are FM count and compliance.

Analysis and Interpretation

Data analysis will be performed by an independent investigator, who is blinded to the treatment groups. The proportion of spontaneous versions following treatment with moxibustion will be compared with that in the controls.

Protocol D

A new drug formulation for pulmonary embolism

Scientific Background

With the global number of hospitalised COVID 19 patients reaching record levels, further attention is drawn to the many complications associated with the disease. In particular, among hospitalised patients, some studies have shown that over a third suffer complications due to blood clots. Clots that make their way into the lungs can cause Pulmonary emboli which when identified is treated with suitable anticoagulation therapy.

Aim

This study aims to test the efficacy of a new drug formulation for the treatment of Pulmonary embolisms associated with COVID 19.

Methods

100 Patients over the age of 60 who return positive D-Dimer results and have a CT confirmed Pulmonary embolism will be invited to participate in this drug trial by requesting their data from their GPs. An intermediary from the manufacturing company will then speak to participants who agree about the pharmacokinetics of the new drug. Allocation to either the placebo or drug wing will be done using the order in which patients are recruited for the study.

Following this, a 30-day supply of labelled tablets will be provided and patients asked to return after completing their course of medication for a follow-up blood test and scan.

Analysis

A 40% reduction in both the size of the embolism and D-Dimer during the follow up will be considered positive results.