Activity 5 – Clinical Trials in Trauma

Introduction

Clinical Trials play an important role in scientific enquiry regarding disease processes and ways in which patients can be treated. Centre for Trauma Sciences research focusses on understanding trauma as a disease and ways in which trauma patients can be treated. Currently, bleeding patients, immune responses after trauma and endothelial function are being studied.

This activity will introduce pupils to a clinical trial, by focussing on important factors such as eligibility criteria, randomisation, interventions vs placebo and data interpretation. They will be required to choose patients, fill out screening logs and interpret the effect of a new drug on bleeding trauma patients.

Aim of activity

This activity aims to highlight the importance of clinical trials by introducing students to the key concepts involved in clinical trials. These key factors include: consent, eligibility criteria, randomisation, intervention vs placebo and data interpretation.

Materials

Each student will need:

- Copy of eligibility criteria
- Access to the patient information sheet
- Worksheet – Screening log

Instructions

1. Begin the lesson by discussing what a clinical trial is with the students. Ensure that they understand the key definitions of: clinical trials; consent; eligibility criteria (inclusion/exclusion); interventions and placebo and randomisation.
2. Introduce students to their task, which will be running through a clinical trial themselves by choosing their patients, deciding how to randomise them and interpreting the results.
3. Tell them that they will be assessing the effect of a new drug on bleeding trauma patients. Explore what they think the inclusion/exclusion criteria should be.
4. Show the pupils the eligibility criteria for the trial: consented; suffered from trauma; aged between 18 and 65; not pregnant; within 2 hours of traumatic injury and currently bleeding.
5. Give the pupils the patient cards and ask them to sort them into patients who are eligible and those who are not.
6. Ask the pupils to fill out the screening log with information about the patients, clearly stating which patients are and are not eligible.

7. Ask the pupils how they think they could randomise the patients into the intervention vs the placebo group.
8. Use the pupil's method of randomisation to allocate the patients to a group
9. Show the patients the results for the patient in the intervention and placebo group
10. Discuss the results with the students, ensure that they understand the differences between the two groups
11. Ask the students to evaluate their trial, discussing whether they would have done anything differently focussing on eligibility and randomisation.

Extension Activities

- Ask students to present the results for the patients in an appropriate graph format
- Discuss the different types of randomised control trials – cross over etc
- Discuss the types of non-interventional research studies such as: cohort, case control etc