

So is it a Clinical Trial?

The problem with clinical trials in recent years is that anything that is classified as a clinical trial has to go through a registry process which includes payment of a fee (which can in some cases at least be a 4-figure sum). This creates problem for research on small scale projects where there is either no specified funding or very limited funding. We want to share our experience of how we overcame the difficulties.

The Problem

We wanted to test whether any antispasticity procedures showed an improvement measurable by automated gait analysis procedures.

Background

There was already ample evidence that the procedures involved were clinically effective. What was not known at the time, and we wished to demonstrate was measurable results on formal gait analysis. Our proposal was to use a before and after test with each patient as acting as their own control. However if this were deemed to be a clinical trial of the substance under test then it would have to be formally registered and we had no funding for this. It was essentially a trainee project to be done in their allocation of research time.

Progression

We had consultation with the Research Department within our own Trust. They have experience of both commercial and non-commercial applications for funding. With their support we were able to write up the project not as a trial of the procedure but as a quantification of the results of a procedure known to have clinical success by new methods. This was then submitted to the relevant authorities and deemed not to be a clinical trial within the meaning of the project.

This did not exempt us from the usual ethical and research governance disciplines. It meant we did not have produce non-existent funds to advance the study.

Learning Point

Be careful how you describe research. Where advice is available from the equivalent of a research department in your Trust, or from those experienced in gaining and administering funds from research make full use of this. Don't be deterred from carrying out a valuable project merely because you can't see your way over all the hurdles at the start.

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