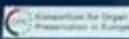




Data Monitoring Committee overseeing multiple international randomised controlled trials



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Background

The Consortium for Organ Preservation in Europe (COPE) focuses on three clinical trials to improve preservation and reconditioning strategies for kidneys and livers for transplantation. The aim is to increase the number and quality of grafts used since the shortage of organs never organs are also procured from higher risk donors contributing greater risk to the recipients.

- WPI - COPE RCT: normothermic machine perfusion versus cold storage in liver transplants
- WPI - PDMP RCT: organotonic hypertonic kidney perfusion during cold storage in extended criteria donor (ECD) kidneys
- WPI - COMBIS RCT: organotonic vs non-organotonic hypertonic machine perfusion in donation after cardiovascular death (DCA) kidney transplantation

Each RCT is led by a chief investigator (CI) in an individual country, but recruits from across different European centres, with 6 countries involved in total. Each RCT is supported by an individual Trial Management Committee but the central management of all three trials as well as the statistical support are based in Oxford. Therefore, a single 'combined' Data Monitoring Committee (DMC) was set up to oversee the three trials. The committee is composed of 5 members from different countries and with different expertise.

Objective

We present our experience using this novel approach together and discuss the benefits and challenges in order to provide a helpful reference to ensure that we consider this option in similar situations.



Pros	Cons
<ul style="list-style-type: none">• Multiple reports for separate at the same time• Difficult when submission not full time on the project• Progress meetings means time a DMC meeting is complete, a data lock is almost inevitable delay required for next one• If recruitment period not long, meetings needs to be more frequent• Early data lock to data for at least one trial is not the most up-to-date meeting difficult to respond to immediate problems early	<ul style="list-style-type: none">• Multiple reports for separate at the same time• Difficult when submission not full time on the project• Progress meetings means time a DMC meeting is complete, a data lock is almost inevitable delay required for next one• If recruitment period not long, meetings needs to be more frequent• Early data lock to data for at least one trial is not the most up-to-date meeting difficult to respond to immediate problems early

Discussion

Multiple trials to a feasible option when the studies are part of the same project and they do not use different populations. This approach is convenient as it facilitates set-up of the committee (including organisation of meetings) and it has the advantage of reducing expenses. Organising multiple reports requires longer times and a high number of meetings, particularly if the same statistical support is embedded in the study from the start, or a larger unit taking the on to the individual trial reports for frequent DMC meetings. This careful consideration of several aspects, like resources and competencies of the staff, workload capacity and time management of the people involved in preparation of the reports.

