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WHY RANDOMIZATION IS AN ETHICAL ISSUE

The central ethical issue raised by clinical trials is usually taken to be that of balancing the welfare of the individuals involved in a trial against the value of the result achieved by the trial ("individual versus collective ethics"). What price – in terms of possible suffering amongst subjects in the trial - is "worth paying" for a really solid, scientifically-validated result, that will then, of course, affect the treatment of many future patients?

A much-discussed case in which this issue arose forcefully is that of trials on ECMO (extracorporeal membraneous oxygenation) as a treatment for neonates suffering from persistent pulmonary hypertension of the newborn.

Most of the discussion of the ethics of this and related cases has been based on the assumption that clinical trials that involve randomisation (RCTs) provide, if not the *only* genuinely scientifically-valid evidence, then certainly much stronger evidence than any other form of trial. The idea that the double blind RCT provides the "gold standard" of proper scientific evidence is almost universally accepted in modern medicine – to the extent that it is often regarded as trivially or definitionally true: an RCT is just what proper scientific method requires when trying to assess the efficacy of a proposed therapy. The 'gold standard' claim is certainly not trivially true – it needs to be argued for. I here examine the arguments that have been given for the special scientific strength of RCTs. And I show that they are much less convincing than is generally believed. The ethical issues look very different in the light of this re-analysis of the evidential strength of the RCT methodology.

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και, με τηλεδιάσκεψη, αίθουσα Σεμιναρίων 2, της Ιατρικής Σχολής
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