Questions and Answers session – 9th July 2020

Please note that the following text is not an accurate reproduction of the minutes of the online session. They have been extensively edited to make it more informative and useful to readers.

Are there any suggestions for cutting down the paperwork for the teams?

The research team themselves found that the patient related paperwork – mainly the questionnaire - were a little bit excessive. We are not really sure why they have decided to pick two quality of life questionnaires that are pretty much equivalent – there may be some redundancy there. Some of the researchers have highlighted this point.

What was the purpose of this trial? What is a phase 3 trial?

A phase 3 trial was what this trial was hoping to be able to run **after** this feasibly trial. This paper was not a phase 3 trial.

A phase 3 trial is mainly to assess the effectiveness of an intervention – normally in a much wider setting than a phase 1 or 2 trial.

Why do you think a hypothesis was not purposed?

They did not purpose a hypothesis because the aim of this study was not to look at clinical outcomes. The aim of this study was to see if they could recruit enough patients to go on and conduct a randomised control trial. So, there was no null hypothesis.

What was the research question?

Can we have an acceptable recruitment rate in a randomised clinical trial designed to identify either equivalence or superiority of laparoscopy vs open in colorectal surgical emergencies.

What was the recruitment rate that the study thought would be good before the start of the study?

They wanted to recruit one patient per site per month and they succeeded in that.

Could you not do some kind of simulation and rely on observational studies of laparoscopic colorectal resections and open resections or pre-existing audits to look at feasibility?
If it is all about recruitment rates why can they not extrapolate information from other recruitment trials in an emergency setting – surely you would get a similar level of recruitment in any acute surgical setting?

The need for a study like this came about because of a trend that has emerged from a few diverticulitis trials that have recently been put out and have failed because they could not hit the recruitment rate that they were expecting to hit.

They could have estimated recruitment rates, and they kind of did, through NELA and that is where they calculated the one patient per site per month from.

Apart from recruitment rate, what do trials of this kind help?

The study also wanted to look at a number of factors apart from recruitment rate for example which questionnaires would be best and if the overall paperwork of the study would be acceptable for the researchers.

Prior to the study, what were the stated requirements that needed to be fulfilled to say that the trial is feasible and acceptable?

Apart from the target of one patient per trial per centre no other factors were really stressed.

Can a feasibility trial be used to find funding for the main trial?

The paper does not make mention of funding in any way. Generally speaking, it is a concept that is valid – you want to show you can conduct a study before you get the money to do it. However, I would suspect that conducting this study would have been quite expensive and used quite a bit of money and resources.

For a lot of trials, the feasibility aspect is normally actually built into the main study and not run as a separate project.