The art of enrolling preterm babies in clinical trials

May 15 2014

Around the world more and more babies are born preterm, according to a WHO report from 2012. Despite medical advances, very small preterm infants may suffer from various complications and diseases, or even die. The EU-funded project NEUROSIS, due to be completed in 2015, has been focussing on a particular complication. "One of themore important complications remains the so-called bronchopulmonary dysplasia (BPD)", says project coordinator Christian Poets, medical director of the

Department of Neonatology at University Children's Hospital Tübingen, in Germany. The project involves a large clinical trial on 863 preterm infants born between the 23rd and 27th week of pregnancy. It aims to assess whether less preterm infants develop BPD and/or die, if they begin inhaling budesonide – a steroidal asthma drug – hours after birth. But a major challenge will be obtaining well-informed voluntary parental consent without adding to the pressure that parents face.

BPD can develop if premature babies whose lungs are not fully developed require artificial ventilation or oxygen. It can impair development; increase the risk of lung diseases later in life or even cause death of babies. A recent review highlights that well-designed controlled trials are urgently needed to assess the benefits and long-term risks of BPD treatments. This includes the so-called inhaled steroids, which have not been tested in preterm infants widely before. A gap the project partners want to fill. By studying the long-term effects of inhaled steroids, "we try to reduce the particular risk for BPD without the known side effects from systemic steroids," Poets says.

But conducting clinical trials on such tiny infants is not an easy task. For example, the babies had to be enrolled in the trial within 12 hours after birth. "This is an almost unreasonable demand for parents who have just had such a small preterm infant," Poets tells youris.com. To be able to make an informed decision, parents received a leaflet outlining the risks and benefits of the study. The various ethics committees had previously approved this information. But "the face-to-face conversation with the parents is most important," Poets says.

But there is concern regarding how these conversations should be conducted. Indeed, telling parents of a very early preterm infant about a randomised controlled trial "is a lot of information at the worst possible time," says Peter Allmark, ethics expert at the Centre for Health and Social Care Research at Sheffield Hallam University, in the UK.

Clinicians could "give the information in chunks that parents can handle," he tells youris.com. An example is the so-called process model of consent. Parents initially receive the most important information about risks and benefits. More information is provided later during the trial.

Allmark stresses that parents must be capable of understanding the information provided. This may be a problem for mothers who have just undergone a traumatic birth. But, according to Allmark, most adults generally have the capacity to give the best possible consent. He also stresses that parents should consent voluntarily to a trial. "Parents may only consent because the treatment is otherwise not available. It is a question of genuine equipoise", he says. That is a trial should be conducted only if there is a genuine doubt whether the tested therapy is actually helpful. In the case of the budesonide study, about 60% of parents that were asked decided to take part in the trial, according to Poets. "That sounds quite good", Allmark says. "If it is 100% it is pretty clear that parents were too desperate," he adds.

Another expert points out more issues. "The emergency situation is really unique. The more time the parents have for their decision the better. Especially in such a stressful situation," says Helen Sammons, associate professor in Child Health at the University of Nottingham, UK. In her view, if there are only 12 hours between birth and the potential start of the treatment, informing the parents before the birth of their child, if possible, should be considered.

Sammons calls for "getting parents involved in the design of trials". For example, trial designers should ask parents to read the information sheets and comment on it. She also welcomes approaches such as in the British BRACELET study. This aims at improving the design of future clinical trials with neonates in intensive care. Amongst other things, this study involved asking parents whose child died during a clinical trial

about their experiences.

But there is also approval for the scale of the project's efforts. "There are so few trials on neonates. It is really good if there are large European studies that are properly designed and include a high number of cases that lead to statistically relevant results," says Sammons. She also holds that public funding is important for this kind of research. "The medicine used in the study is a very old one. No pharmaceutical company would have funded it," Sammons tells youris.com.

Provided by Youris.com

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