

Treating lung disease in infants

May 15 2014, by Constanze Böttcher

Steroids used to treat the lungs of preterm infants have come under scrutiny. Now a large clinical trial assesses whether inhaling steroids is safe and useful.

The [intensive care](#) of neonates has advanced considerably in the last decades. But very early [preterm infants](#) are still at risk of dying. Artificial ventilation or additional oxygen is often needed to support the lungs of the [premature babies](#). But these measures may also cause other problems. For example, [preterm babies](#) may develop a [lung disease](#) called bronchopulmonary dysplasia (BPD). The EU-funded project [NEUROSIS](#), due to be completed in 2015, aims at assessing the potential risks and benefits of so-called inhaled steroids to treat BPD. Across European hospitals, a large clinical trial on preterm infants born between the 23rd and 27th week of pregnancy is conducted. Here, project coordinator Christian Poets medical director of the department of neonatology at University Children's Hospital Tübingen, Germany talks to youris.com about the need for such a clinical trial. And why the study's results will be useful regardless of the outcome.

Why is it important to study inhaled steroids in preterm infants?

About 20% of very low birth-weight preterm infants are at risk of developing chronic lung disease. This so-called bronchopulmonary dysplasia (BPD) is an inflammatory disease. Therefore, steroids were used for many years to prevent BPD. But if these steroids are administered via the blood intravenously they may cause an increased

risk of cerebral palsy. This means that the child may develop movement disorders that lasts its entire life. Therefore, the use of these so-called systemic steroids has decreased drastically since this risk was detected around the turn of the millennium. Maybe, we paediatricians have even reduced its use to such an extent that more children die. There has always been the option to administer steroids directly to the lung via inhalation. But except for one study, there have not been any larger controlled [clinical trials](#) on inhaled steroids so far.

How was the study designed?

Altogether, we recruited 863 children in 42 study centres. The children had to be enrolled within 12 hours after birth. We chose the dose of the asthma drug budesonide based on the results of the previous study by colleagues in the USA. Neither the clinical team nor the medial researchers knew whether the baby received the drug or a placebo. To exclude any long-term side effects, all infants are checked again at two years of age. The treatment period has now been finished. But we are still analysing the data and collecting data from the two-year follow-up.

Are there alternative ways to prevent lung disease in preterm infants?

Generally, it is a good idea to provide as little [artificial ventilation](#) as possible. But there are many children where measures such as no ventilation or as gentle ventilation as possible do not suffice. Another effective measure is to treat women who expect a preterm delivery with steroids prior to birth to improve lung maturation of the foetus. This is, for example, well established in Germany. Here, about 95% of women at risk receive such so-called antenatal steroids. But, while this treatment lowers the risk of preterm infants to develop BPD, it does not reduce it to zero.

What is the expected impact of the study?

The results are important in any case. If it turns out that using inhaled steroids can actually lower the rate of BPD in early preterm infants, this will certainly become a routine measure. But if the results are negative, you can avoid an unnecessary and costly treatment in the future. You can even prevent harm by not giving this type of medication.

What motivated you to initiate this study?

It is generally a problem that many medications are not being tested in children. I previously worked on older children with lung diseases that were successfully treated with inhaled steroids. When I started working with neonates and introduced the [inhaled steroids](#) I faced the dilemma of applying a medication that was not approved. So, when the EU published a list of drugs, including steroids that are used for children but that are not approved, we decided to file an application.

Do you think that more clinical trials should be performed on neonates?

Yes, definitely. We are acting in a black box. We do not really know what we are doing. We treat the most sensitive human beings with medication that is least tested and approved. Of course, the ethics committees have to strictly control such studies. I also think it is important to have these studies funded by public authorities, such as the EU, that take into account the public interest. And not a company's economic interests.

Provided by Youris.com

Citation: Treating lung disease in infants (2014, May 15) retrieved 20 April 2024 from <https://medicalxpress.com/news/2014-05-lung-disease-infants.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.