Efficacy and Safety of Inhaled Budesonide in Very Preterm Infants at Risk for Bronchopulmonary Dysplasia

Result in Brief

Project information

NEUROSIS

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Project website

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Closed project

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Coordinated by:
EBERHARD KARLS UNIVERSITAET TUEBINGEN

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Improving lung disorders in premature babies

Bronchopulmonary dysplasia (BPD) is a chronic lung disorder that is most common among children who are born prematurely. A safe therapy for BPD treatment would be extremely valuable from an individual patient as well as an economic health care perspective.

BPD involves abnormal development of lung tissue, and is characterised by inflammation and scarring in the lungs. It develops most often in premature babies, who are born with underdeveloped lungs. BPD results in significant morbidity and mortality.

Systemic corticosteroids are effective in preventing BPD, but their use is practically prohibited given their adverse effects on neurodevelopment. Early inhalation of corticosteroids is associated with pulmonary benefits, but its effect on survival without BPD and on neurodevelopment remains unclear.

The EU funded the NEUROSIS project to determine whether early inhalation of corticosteroid budesonide
improves survival without BPD at 36 weeks of gestation in infants born between 23 and 27 weeks. NEUROSIS is an international multi-centre randomised controlled blinded study in a population of 850 pre-term infants.

Approvals from the national competent authorities and the research ethics boards have been obtained in all countries. The project will focus on data analysis and the follow-up of neurodevelopmental assessment. NEUROSIS is one of the largest randomised controlled studies in pre-term neonates ever conducted in Europe. Its results have the potential to make an important impact on the economics of premature baby health care.

Keywords

Bronchopulmonary dysplasia, corticosteroids, budesonide, randomised controlled study

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