ISRCTN80181452 https://doi.org/10.1186/ISRCTN80181452

Neonatal European Study of Inhaled Steroids

Submission date 21/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/07/2010	**Overall study status** Completed	
Last Edited 28/08/2018	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01035190

Protocol serial number
Grand_Award_Health-F5_2009-223060

Study information

Scientific Title
Efficacy and safety of inhaled budesonide in very preterm infants at risk for bronchopulmonary dysplasia: a phase III trial

Acronym
NEuroSIS

Study objectives
Early prophylactic inhalation of budesonide reduces the absolute risk of bronchopulmonary dysplasia (BPD) or death in preterm infants born less than 28 weeks gestational age by 10%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Independant Ethics Committee (IEC) of the University of Tuebingen approved on the 19th of November 2009

Primary study design
Interventional

Study design
European multicentre randomised placebo controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bronchopulmonary dysplasia

Interventions
Active substance (inhaled Budesonide - 200 µg per puff) and placebo will be given from:
Day 1 till Day 14 2 x 2 puffs per day and from Day 15 onward 2 x 1 puff per day.

Inhalation is performed till the patients:
1. Are off supplemental oxygen and off mechanical ventilation (or CPAP) for at least 72 hours, or
2. Have reached 32 + 0 weeks of gestational age irrespective ventilatory/oxygen status

Follow up will be performed at 18 - 22 months of corrected age.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Budesonide

Primary outcome(s)
Combination of BPD or death at 36 weeks gestational age

Key secondary outcome(s)

1. All cause mortality at 36 weeks gestational age
2. BPD at 36 weeks gestational age
3. Duration of positive pressure respiratory support and supplemental oxygen
4. Neurodevelopmental disability at 18 - 22 months corrected age
5. Adverse treatment effects
6. All grades of intraventricular haemorrhage (IVH) and/or peri-ventricular leukomalacia (PVL)
7. Patent ductus arteriosus (PDA)
8. Intestinal perforations and/or necrotising enterocolitis (NEC) (Bell stage 2 - 3)
9. Retinopathy of prematurity (ROP)
10. Culture proven infections
11. Growth
12. Length of hospitalisation
13. Infants requiring re-intubation

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Gestational age of 23 0/7 - 27 6/7 weeks
2. Postnatal age less than 12 hours
3. Necessity for any form of positive pressure support (mechanical or nasal ventilation or continuous positive airway pressure [CPAP])
4. Singleton or second born in case of multiple pregnancy
5. Parental consent for participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Clinical decision not to administer therapies (infant not considered viable)
2. Dysmorphic features or congenital malformations that adversely affect life expectancy or neurodevelopment
3. Known or suspected congenital heart disease (not including a persistent ductus arteriosus and /or an atrial septum defect)

Date of first enrolment
01/04/2010

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
United Kingdom

Czech Republic

Finland

France

Germany

Israel

Netherlands

Study participating centre
Calwerstrasse 7
Tuebingen
Germany
72076

Sponsor information

Organisation
University Children`s Hospital of Tuebingen (Germany)

ROR
https://ror.org/03esvmb28

Funder(s)

Funder type
Government

Funder Name
European Union (EU) (Belgium) - Seventh Framework Programme (FP7) for Research and Technological Development (RTD) (ref: 223060)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/10/2015		Yes	No
Results article	results	11/01/2018		Yes	No
Protocol article	protocol	01/07/2010		Yes	No