

Neonatal European Study of Inhaled Steroids

Submission date 21/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/08/2018	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

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 Independent Ethics Committee (IEC) of the University of Tuebingen approved on the 19th of November 2009

Study design

European multicentre randomised placebo controlled parallel group trial

Primary study design

Interventional

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/03esymb28>

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes