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Neonatal Insulin Replacement Therapy in Europe

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/06/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0544112291 (pilot study reference on NRR)

Study information

Scientific Title

Acronym
NIRTURE

Study objectives
It is proposed that relative insulin deficiency in the very low birth weight baby leads to profound catabolism, insulin resistance and hyperglycaemia during the first week of life. High blood glucose levels may lead to osmotic diuresis, intraventricular haemorrhage and increase the risk of sepsis. Insulin deficiency may contribute to slow weight gain and impaired IGF-I generation which could have implications for risk of retinopathy, brain growth and later neurodevelopmental outcomes. It is hypothesised that early intervention with continuous insulin replacement will prevent catabolism and improve glucose control, and could reduce neonatal morbidity and mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Hyperglycaemia

Interventions
Intervention: Insulin aspart (NovoNordisk) for intravenous injection. Insulin will be given intravenously at a fixed rate of 0.05 u/kg/hour. It will be prepared as a standard strength solution of 25 units/kg insulin aspart in 50 ml of 0.9% sodium chloride to run at 0.1 ml/hour, equivalent to 0.05 u/kg/hour.

The control intervention will be standard neonatal care.

All babies will be monitored using the Minimed continuous glucose monitoring system (CGMS) for 7 completed days.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Death on or before expected date of delivery.

Key secondary outcome(s))
1. Episodes of sepsis in the first 2 weeks
2. Growth
3. Incidence of necrotizing enterocolitis
4. Retinopathy of prematurity
5. Incidence of intracranial haemorrhage
6. Chronic lung disease
7. Death within and including the first 28 days after delivery
8. Days of Neonatal Intensive Care

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Birth weight <1500 g
2. Requiring intensive care and in whom it is considered appropriate to continue intensive care
3. Less than 24 hours of age
4. Written informed parental consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Maternal diabetes including gestational diabetes
2. Babies where the appropriateness of continuing intensive care is being discussed
3. Major congenital anomalies

Date of first enrolment
25/04/2002

Date of final enrolment
01/01/2008

Locations

Countries of recruitment

United Kingdom

England

Belgium

Netherlands

Spain

Study participating centre
Box No 116
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Industry

Funder Name
Medtronic and Novonordisk

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	30/10/2008		Yes	No
Results article	results	01/05/2014		Yes	No
Protocol article	protocol	10/08/2007		Yes	No