

# Neonatal Insulin Replacement Therapy in Europe

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/06/2014	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Prevention

## Participant information sheet

## 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 measure**

Death on or before expected date of delivery.

**Secondary outcome measures**

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

**Overall study start date**

25/04/2002

**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

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

500

**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**

Belgium

England

Netherlands

Spain

United Kingdom

**Study participating centre**

Box No 116

Cambridge

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CB2 2QQ

**Sponsor information****Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

**Sponsor details**

R&D Department

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.addenbrookes.nhs.uk>

**ROR**

<https://ror.org/04v54gj93>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Medtronic and Novonordisk

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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?
<a href="#">Protocol article</a>	protocol	10/08/2007		Yes	No
<a href="#">Results article</a>	results	30/10/2008		Yes	No
<a href="#">Results article</a>	results	01/05/2014		Yes	No