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MIND: Melatonin Neuroprotection Dosage Study

Submission date	Recruitment status
24/06/2010	No longer recruiting
Registration date	**Overall study status**
24/06/2010	Completed
Last Edited	**Condition category**
22/03/2016	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
2007-007156-33

ClinicalTrials.gov (NCT)
NCT00649961

Protocol serial number
4169; G0502100

Study information

Scientific Title
Melatonin as a novel neuroprotectant in preterm infants - Dosage study

Acronym
MIND

Study objectives
Preterm babies are at risk of brain injury. Melatonin, a naturally occurring hormone, may reduce this risk. The unborn baby receives melatonin from the mother but following premature delivery there maybe a period of prolonged melatonin deficiency. This deficiency may be harmful because studies suggest that melatonin is important in protecting the brain and reducing the risk of brain injury after preterm birth. The purpose of this study is to find the ideal dose of melatonin to give to preterm babies. We intend to study a total of 24 babies less than 31 weeks gestation and who are less than 7 days old.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hammersmith and Queen Charlottes Hospital Research Ethics Committee, 23/04/2008, ref: 08 /H0707/33

Study design
Multicentre non-randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
The proposed clinical trial is a single dose, open label, dose escalation pharmacokinetic study in preterm infants less than 31 weeks gestation to achieve adult peak blood concentrations of melatonin (200 - 250 pmol/L). The trial will be a multicentre study based in the Neonatal Intensive Care Units of United Kingdom. A single intravenous infusion of melatonin will be given to each infant maximum over 6 hours once in the first 7 days of life. The starting dose is 0.1 microgram/kg/hr which will be increased or decreased incrementally in subsequent groups of infants until the desired melatonin concentration is achieved. A maximum of 24 preterm babies less than 31 weeks gestation will be recruited in this study. Four blood samples (0.5 - 1 ml) will be collected at various time points of the intravenous infusion along with bag urine samples to evaluate the pharmacokinetics profile of melatonin. Patients will followed up as routine local neonatal protocol.

Follow-up length: 0 months
Study entry: registration only

Intervention Type

Drug

Phase
Phase II

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

Primary outcome(s)
Serum melatonin level 200 - 250 pmol/L, measured at 6 hours after infusion started.

Key secondary outcome(s))
Pharmacokinetics profile of melatonin in preterm infants

Completion date
25/12/2010

Eligibility

Key inclusion criteria
1. Infants born at less than 30 weeks gestation, either sex
2. No major congenital malformation
3. No cystic periventricular leukomalacia (cPVL) or haemorrhagic parenchymal infarction (HPI) on cranial ultrasonography
4. Parental consent given
5. Can begin treatment within 24 hours of birth

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Major congenital malformation
2. Cystic periventricular leucomalacia (cPVL) or haemorrhagic parenchymal infarcts (HPI) on cranial ultrasonography

Date of first enrolment
18/05/2010

Date of final enrolment
25/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College London (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0502100)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/11/2013		Yes	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes