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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

EudraCT/CTIS number
2007-007156-33

IRAS number

ClinicalTrials.gov number
NCT00649961

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at http://www.imperial.nhs.uk/discoveryscanning/index.htm

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 measure
Serum melatonin level 200 - 250 pmol/L, measured at 6 hours after infusion started.

Secondary outcome measures
Pharmacokinetics profile of melatonin in preterm infants

Overall study start date
18/05/2010

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

Age group
Neonate

Sex
Both

Target number of participants
Planned sample size: 24; UK sample size: 24

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
England

United Kingdom

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
ICCH Building
59 North Wharf Road
London
England
United Kingdom
W2 1LA

Sponsor type
University/education

Website
http://www3.imperial.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Basic results				No	No
Results article	results	01/11/2013		Yes	No