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Melatonin as a novel neuroprotectant in preterm infants - trial study

Submission date	Recruitment status	[_] Prospectively registered
06/01/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/01/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2020	Neonatal Diseases	

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
2008-004740-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8659

Study information

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

Acronym
MINT

Study objectives
Premature babies are at risk of brain injury. Brain injury may lead to long term complications ranging from learning disabilities to cerebral palsy. No drug has been shown to protect these vulnerable babies from brain injury after early delivery. Experimental studies suggest that melatonin may reduce the risk of brain injury. The unborn baby receives maternal melatonin but following premature delivery, prolonged melatonin deficiency is noted, which may be harmful.

Aim:
To prove that melatonin given daily for 7 days after birth may reduce the risk of brain injury following preterm birth.

The information we obtain from this study will help decide whether melatonin is a promising treatment for preterm brain injury and would lead to further larger clinical trials to find out if it should be made available to other preterm babies in the future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 04/08/2011 ref: 11/LO/0839

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Brain injury in premature babies

Interventions
This study will be a randomised controlled trial of 60 preterm infants less than 31 weeks gestation. It will be a multicentre study involving Imperial College Healthcare NHS Trust (Queen Charlottes' and Chelsea Hospital and St Mary's Hospital), Medway Maritime NHS Trust and St Thomas' Hospital, London UK.

Routine cranial Ultrasound Imaging prior to starting treatment in the first 48 hours. Following informed parental consent, infants will be randomised to treatment with melatonin or normal saline (placebo) as intravenous infusion over 2 hours daily for 7 days starting from less than 48 hours of age. Clinical signs will be monitored continuously to confirm safety.

The main outcome of the study will be changes on Magnetic Resonance Imaging (MRI) studies performed at term corrected age. Blood and urine will be taken at the same time as routine tests if possible to look at the melatonin levels. Donor and maternal breast milk will also be collected. All babies will continue to receive standard intensive care treatment. Participation will not affect the baby's care or prolong the hospital stay.

The following will be measured:
1. Blood samples will be collected for melatonin levels at various time points during the inpatient stay
2. Maximum trial related blood loss <3% of total blood volume
3. Magnetic resonance imaging, 45-60 min scaning
4. Maternal Milk 1-2ml collection - milk expressed by mothers are sent off to a laboratory for melatonin dosage analysis by the clinical and research team
5. Urine samples will be collected non-invasively in a urine collection bag or cotton wool over 23 hours depending on local care given to the preterm infants.

Intervention Type
Drug

Phase
Phase II/III

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

Primary outcome measure
Preserved fractional anisotropy measured by Tract-Based Spatial Statistics (TBSS) on diffusion tensor MRI at term corrected age measured at end of study

Secondary outcome measures
1. MR imaging at term corrected age measured at end of study
2. Pharmacokinetics of melatonin
3. Population pharmacokinetics of melatonin

Overall study start date
01/11/2011

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Infants born less than 31 weeks gestation who are less than 48 hours old
2. Parental consent for participation has been given

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Those with major congenital malformation
2. Those with cystic periventricular leucomalacia (cPVL)
3. Those with haemorrhagic parenchymal infarcts (HPI) on cranial ultrasonography prior to enrolment

Date of first enrolment
01/11/2011

Date of final enrolment
01/07/2014

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
School of Medicine
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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)

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			28/05/2020	No	No
HRA research summary			28/06/2023	No	No