

Melatonin as a novel neuroprotectant in preterm infants - trial study

Submission date 06/01/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/01/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/05/2020	Condition category Neonatal Diseases	☐ 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)
2008-004740-36

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised interventional trial

Study type(s)

Diagnostic

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 scanning
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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

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)

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?
Basic results			28/05/2020	No	No
HRA research summary			28/06/2023	No	No