



Benefits

Babies will receive a new potential treatment to protect their brain after HIE.

Babies will receive optimal neonatal care and monitoring - including detailed monitoring of brain electrical activity (aEEG/EEG) and brain tissue oxygen levels (NIRS).

Risks

As this is the first time that we will be treating HIE with this preparation of melatonin, we will be carefully monitoring for any potential side-effects.

There is a small chance that the blood pressure (BP) may drop, which we can treat with medicines. Babies may also become sleepy, which may be beneficial for comfort during cooling.

There may also be associated risks that we do not know about. If we have any concerns, the treatment will be stopped, and you will be informed.

What's next?

We hope you will choose to take part in this research study.

You are free to withdraw at any point. Whether you chose take part or not, it will not affect the rest of your baby's care.

As you are making your decision, a research doctor is available to help with any questions you may have.

Glossary

Electroencephalography (aEEG/EEG)

Your baby's electrical brain activity will be continuously monitored using painless sensors placed on their head.

Near-Infrared Spectroscopy (NIRS)

Harmless light to help us understand how well the brain is receiving and using oxygen.

Cranial Ultrasound

Bedside scan that assesses the structure of the brain and looks for bleeding or changes caused by HIE.

Magnetic Resonance Imaging and Spectroscopy (MRI/MRS)

Detailed brain scans that assess possible structural and chemical changes in the brain after HIE. Babies may receive sedation during these scans, but it's no more than for standard MRIs.

Additional Blood Tests

A max of 8ml (1 dessert spoon) over the whole study. This is to check melatonin & ethanol levels, and an optional biomarker study. The optional study aims to help us understand HIE and identify new blood tests for HIE.

Data Protection

All data for research purposes will be pseudo-anonymised and kept safe and secure. Please see attached detailed patient information sheet to learn more about your data.



The Study Team

The ACUMEN Study is overseen by **Professor Nikki Robertson** at University College London.

Nikki is a neonatal consultant who has been researching melatonin as a medicine in babies for over 20 years.

This study has obtained ethics approval from the UCL Life and Medical Sciences Research Ethics Committee.

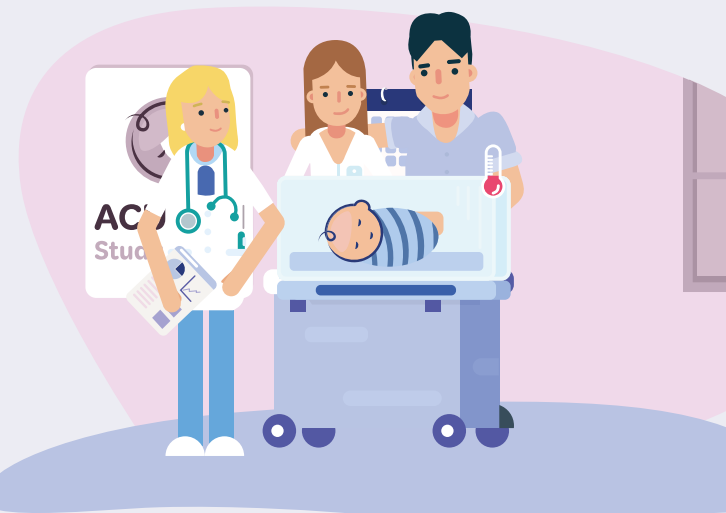


Medical
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ACUMEN Study

Acute High Dose Melatonin To Improve Outcomes In Encephalopathy Of The Newborn





What is HIE?

Hypoxic Ischaemic Encephalopathy (HIE) occurs when a baby does not receive enough oxygen and blood flow to the brain around birth.

When this happens, the body may produce harmful chemicals that continue to injure the brain.

By now, the doctors will be cooling your baby for 72 hours. Research has shown that this decreases the impact of HIE, but some babies may still have long-term problems.

What is the ACUMEN study?

The ACUMEN study is researching an additional treatment for HIE: melatonin. It will be the first time we will be using this preparation of melatonin as a treatment in humans for HIE.

Melatonin is a hormone that our body naturally produces. It is safely used to treat sleep problems in children and jet-lag in adults.

For HIE, melatonin works by mopping up harmful chemicals, reducing inflammation and preventing cell damage.

We will need to give higher doses of melatonin to protect the brain than we do to treat sleep problems.

What will happen during the ACUMEN study?

Your baby will receive the same clinical care as all babies with HIE.

As part of the ACUMEN study, they will also receive 6 doses of melatonin during cooling. The first dose must be given within 6 hours of birth.

Melatonin is given through the vein (intravenous). It is dissolved in a small amount of ethanol (alcohol), which is already present in other medicines given to babies.

Your baby will receive detailed monitoring of the brain and we will be taking additional blood tests.



Vital Signs
Monitoring



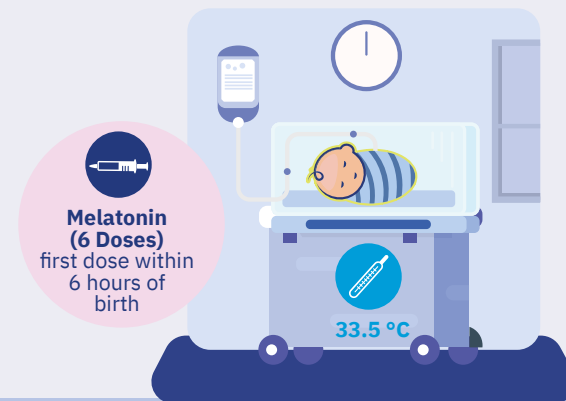
aEEG/EEG
Brain Wave
Monitoring



Cranial
Ultrasound
Brain Structures



NIRS
Brain Tissue
Oxygen Levels



Pathway of Care for all Babies with HIE



Birth



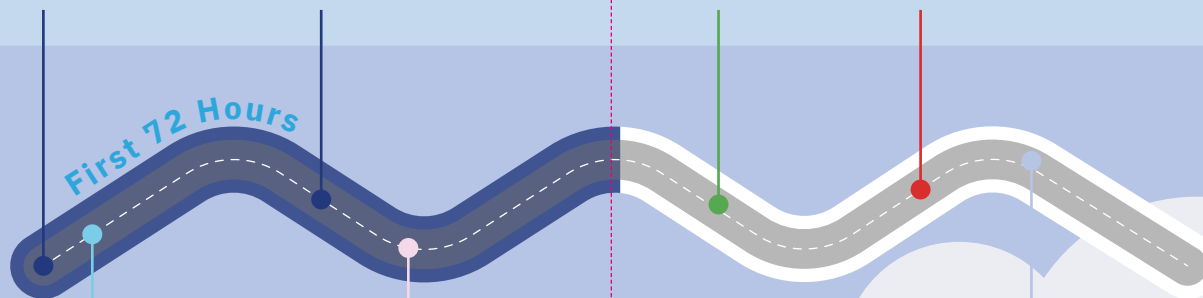
Cooling



MRI / MRS



Home



ACUMEN Study



Melatonin
6 Doses



Blood Tests
For melatonin and ethanol levels
and researching new tests for HIE



3 Months
Hospital
Appointment