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An open-label study followed by a double-blind randomised comparison of the effect of sedation versus melatonin combined with sedation in children undergoing magnetic resonance imaging (MRI)

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 18/05/2009	**Condition category** Other	[_] 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

Protocol serial number
N0012128200

Study information

Scientific Title

Study objectives
How effective is melatonin when combined with other sedatives for sedation of children for MRI?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Not Applicable: Magnetic resonance imaging (MRI)

Interventions
1. Melatonin and combined sedatives
2. Melatonin

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Time taken to fall asleep for scanning

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/09/2003

Eligibility

Key inclusion criteria
Children undergoing MRI

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2003

Date of final enrolment
30/09/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Anaesthetics
London
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Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Great Ormond Street Hospital for Children NHS Trust/Institute of Child Health (UK)

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	01/08/2006		Yes	No