

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 ☒ 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

Contact name

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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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

United Kingdom

WC1N 3JH

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