

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/05/2009	Condition category Other	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet

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 measure

Time taken to fall asleep for scanning

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2003

Completion date

30/09/2003

Eligibility

Key inclusion criteria

Children undergoing MRI

Participant type(s)

Patient

Age group

Child

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

Anaesthetics
London
United Kingdom
WC1N 3JH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

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

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?
Results article	results	01/08/2006		Yes	No