

# 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)

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/05/2009	<b>Condition category</b> Other	<input type="checkbox"/> 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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## 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?
<a href="#">Results article</a>	results	01/08/2006		Yes	No