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Rocuronium requirements on the Paediatric Intensive Care Unit: the value of monitoring neuromuscular function

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/09/2013	Nervous System Diseases	[ ] Record updated in last year

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
N0045125254

Study information

Scientific Title

Study objectives
Does monitoring neuromuscular function on PICU (Paediatric Intensive Care Unit) have any advantages over standard practice of clinical assessment of neuromuscular function/drug requirements?

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
Nervous System Diseases: Neuromuscular function

Interventions
Patients randomly allocated to received either standard management of NMBD (neuromuscular blocking drug) administration or protocol driven according to monitored neuromuscular function.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Total amount of NMBD administered
2. Speed of recovery or neuromuscular function once NMBDs stopped
3. Complications related to residual NM paralysis

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2002

Completion date
31/05/2003

Eligibility

Key inclusion criteria
30 patients under the age of 16 years requiring administration of Rocuronium to facilitate mechanical ventilation for more than 48 hours.

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2002

Date of final enrolment
31/05/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Children's Hospital
Birmingham
United Kingdom
B4 6NH

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
Birmingham Children's Hospital NHS Trust (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