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Comparison of the response observed in the dominant and non-dominant hands when assessing neuromuscular block using the TOF-Watch® SX

Submission date 30/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/10/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/03/2017	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Rosemary Hogg

Contact details
Department of Anaesthetics & Intensive Care Medicine
Queens' University Belfast
2nd Floor, Mulhouse Building
Grosvenor Road
Belfast
United Kingdom
BT12 6BJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RGHT000353

Study information

Scientific Title
Comparison of neuromuscular monitoring in the dominant and non-dominant hand using the TOF-Watch® SX: a single-centre randomised controlled trial

Study objectives
Is there a difference in the response observed between the dominant and non-dominant hand when using acceleromyography to monitor neuromuscular blockade?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee (HSC REC 3) (Northern Ireland), 23/07/2009, ref: 07/NIR03/1

Study design
Randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Routine surgery/neuromuscular block

Interventions
After pre-oxygenation, all patients will receive a standard anaesthetic regimen consisting of intravenous infusions of propofol (0.1 - 8.0 µg/ml) and remifentanil (0.1 - 1.0 µg/kg/min) for induction and maintenance of anaesthesia. After induction, monitoring will be commenced on both arms using the TOF-Watch® SX. The monitors will be applied to the skin over the ulnar nerve at the wrist and calibrated according to Good Clinical Research Practice guidelines. After stabilisation of the TOF-Watch® SX trace in both arms, rocuronium (0.6 mg/kg) will be administered, following which tracheal intubation will be performed.

Surgery will be continued as normal with monitoring continuing until extubation. Reversal with neostigmine will be performed as required.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Time to return of TOF (train-of-four) ratio to 0.9

Secondary outcome measures
1. Tme to onset of block
2. Time to return of T1 to 25%

Overall study start date
01/04/2008

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. American Society of Anaesthesiologists (ASA) grade I - III
2. Aged 18 - 65 years, either sex
3. Undergoing planned, elective surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20 patients

Key exclusion criteria

1. Patients with known neuromuscular disease
2. Patients on medication known to interact with neuromuscular blocking agents
3. Pregnancy
4. Patients with known allergy to neuromuscular blocking agents
5. Patients with a known or suspected risk of difficult intubation

Date of first enrolment
01/04/2008

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queens' University Belfast
Belfast
United Kingdom
BT12 6BJ

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Royal Group of Hospitals
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BJ

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Belfast Health and Social Care Trust (UK) (ref: RGHT000353)

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