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Nerve block simulation training and translation to patient care

Submission date
07/03/2018

Recruitment status
Stopped

Registration date
01/05/2018

Overall study status
Stopped

Last Edited
20/10/2022

Condition category
Surgery

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background:
In ultrasound-guided regional anaesthesia, a needle is inserted through skin under ultrasound guidance and rests very close to, but not touching, a target nerve. Local anaesthetic renders arms and legs completely numb for surgery. This means that patients who are elderly, obese, diabetic or ill can be operated on without resorting to general anaesthesia, which means there are more likely to recover quicker, and often go home soon after their operation.
However, people are unaware that anaesthetists (doctors specialised in inducing unconsciousness and preventing pain) first practice inserting needles on patients. This can expose patients to risks including repeated insertion attempts, severe pain and electrical shocks down the arm or leg, or even anaesthetic-induced convulsions or cardiac arrest. Practical training courses are available to anaesthetists but trainees mainly attend them after they have already started to perform nerve blocks on patients. Teaching is not measured or evidence based. For an educational course to have an impact, it must not just improve skills on the day, but maintain skills such that performance on a patient 2 to 3 months later is better than it otherwise would have been, had no training taken place. Twelve controlled studies have investigated the role of nerve block simulation training with one showing specific benefit when skills were translated to improved patient care.
In Dundee, we have the resource and experience to remedy this problem. We have the best simulator of regional anaesthesia – the soft embalmed Thiel cadaver (human corpse) that looks like and feels like a living patient after it has been preserved by soaking in vats of acid and salts for 6 months. Nerves and muscle are seen readily on ultrasound. Injection of fluid around nerves behaves like that seen in patients and disperses as quickly because the cadaver tissue is still elastic. Hundreds of injections can be performed on the cadaver without damage.
We have also developed objective measures of performance that reflect the quality and outcome of nerve block. Using a repeated questionnaire method, 16 UK experts identified 17 steps that are key to success and 21 errors to be avoided. We also conducted the largest, most detailed study of eye tracking in anaesthesia. Eye tracking gives an idea of what people see and how they make decisions. Special glasses identify the movement of the pupil during the nerve block process, tracking what the trainee focuses on and when they glance away from the site of interest. Our results offer very detailed analysis of performance that differentiate between all levels of performance.

Who can participate?
Trainee anaesthetists in Scotland

What does the study involve?
We want to conduct three studies that test the effect of simulator training on clinical performance and patient outcome. We want to ensure our step and error metrics are reliable. Then we want to see if extra training on our soft embalmed cadaver is better than standard course training alone. We will then see if applying a well-established and proven educational method called mastery learning to cadaver simulator training improves performance when anaesthetists perform nerve blocks on patients.

What are the possible benefits and risks of participating?
There are no identifiable risks to participating anaesthetists nor additional risks to patients. Patients and anaesthetists may benefit from the extra training.

Where is the study run from?
Ninewells Hospital, Dundee.

When is the study starting and how long is it expected to run for?
The study is starting in June 2018 and finishing in November 2020.

Who is funding the study?
The National Institute for Academic Anaesthesia is funding the study via a British Journal of Anaesthesia/Royal College of Anaesthetists Project Grant.

Who is the main contact?
Professor Graeme McLeod, g.a.mcleod@dundee.ac.uk.

Contact information

Type(s)
Public

Contact name
Prof Graeme Mcleod

ORCID ID
http://orcid.org/0000-0001-5931-1362

Contact details
Institute of Academic Anaesthesia
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY
+44(0)7974440848
g.a.mcleod@dundee.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R&D2017AN04

Study information

Scientific Title
Does cadaver simulation training offer best clinical performance behaviour during ultrasound-guided regional anaesthesia?

Study objectives
Our hypothesis is that additional training in ultrasound-guided regional anaesthesia on the soft embalmed cadaver simulator using mastery learning and feedback translates to improved clinical performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethical submission was sent on the UK IRAS system to the North East – Newcastle & North Tyneside 1 Research Ethics Committee on 16/03/2018 (REC reference: 18/NE/0118). Approval had not yet been granted as of 02/04/2018.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Training of anaesthetists to perform interscalene nerve block

Interventions

WORKPLAN WP1 STEP AND ERROR METRIC VALIDATION

Milestone 1.1 Train and record training videos of interscalene block on soft embalmed cadaver sufficient to illustrate all the steps and errors chosen from the Delphi questionnaire, including sentinel errors.
Milestone 1.2 Test performance on soft embalmed cadavers

In order to achieve Milestone 1.1 we will conduct an RCT on the soft embalmed cadaver as follows:

Collect baseline data:
• Trainee and trainer characteristics
• Trainee and trainer baseline testing of visuo-spatial ability and psychomotor ability.
Visuo-spatial ability will be tested using Mental Rotation Tests (MRT), described by Roger Shepard and Jacqueline Metzler in 1971 and adapted by Peters M (2008) Applications of mental rotation figures of the Shepard and Metzler type and description of a mental rotation stimulus library (Brain Cogn. 2008 Apr;66(3):260-4.)
Psychomotor ability will be tested using the Projected Image Performance Testing (Zig-Zag Test) Tiplady B, Barton C, Dudman A, Drummond G, Wright P. Zig-Zag tracking: a test of psychomotor speed and accuracy designed for repeated administration. Poster presented at the British Association of Psychopharmacology, Harrogate, UK, July 26–28, 2004.

Deliver standard teaching that reflects delivery at UGRA courses
• Twenty min. lecture on the conduct of interscalene block, highlighting all the necessary steps to perform and errors to avoid, before and during the block.
• Trainee ultrasound scanning of a volunteer for 20 min.
• Needle practice on a pork phantom with embedded tendon for 20 min.

In order to achieve Milestone 1.2 we will test as follows:

Assess performance:
We will conduct a randomised controlled trial (RCT) of 6 trainees and 6 consultant experts randomly allocated by computer software to conduct an interscalene block on one of 6 cadavers. All participants will wear wireless eye tracking spectacles and have performance videoed by two fixed cameras, one focused on the transducer and the other further back focused on the screen and transducer. Secondary end – points will be number of eye gaze fixations and eye glances.

WORKPLAN WP2: CHOOSE TYPE OF SIMULATOR THAT BEST ENHANCES CLINICAL PERFORMANCE BEHAVIOUR DURING UGRA
Milestone 2.1 Train and video-record nerve block skills of trainees on either pig shoulder or soft embalmed Thiel cadaver.
Milestone 2.2 Test trainees by conducting a clinical RCT

In order to achieve Milestone 2.1, we will:
Collect baseline data:
• Trainee characteristics
• Trainee baseline testing of visuo-spatial ability and psychomotor ability.

Deliver standard teaching that reflects delivery at UGRA courses
• Twenty minute lecture on the conduct of interscalene block, highlighting all the necessary

steps to perform and errors to avoid, before and during the block.
• Trainee ultrasound scanning of a volunteer for 20 min.
Needle practice on a blue plastic phantom with embedded tendon for 20 min.

Randomly allocate trainees, to training on a shoulder of pork specimen or a soft embalmed Thiel cadaver
All participants will wear wireless eye tracking spectacles and have performance videoed by two fixed cameras, one focused on the transducer and the other further back focused on the screen and transducer. Procedures will be video recorded at 20, 40 and 60min.

In order to achieve Milestone 2.2 we will:
Assess clinical performance:
Trainees will conduct clinical interscalene nerve block in Perth Royal Infirmary or Stracathro Hospital, NHS Tayside. The NHS Tayside Human Resources department will issue clinical access contracts on receipt of evidence of employment, GMC registration, defence union payment, and health checks. Clinical blocks will be performed on patients, 2 days and 6 weeks after training.
All participants will wear wireless eye tracking spectacles and have performance videoed by two fixed cameras, one focused on the transducer and the other further back focused on the screen and transducer.

Measure the primary end point - the number of steps and errors assessed

Measure secondary end-points:
• Number of eye gaze fixations and eye glances conducting clinical interscalene block
• 9-point validated global rating scale (GRS) for summative assessment
• Quality of anaesthesia (preoperative and hourly recovery room pain scores at rest and movement using a 100-mm visual analogue pain scale; onset and distribution of sensory and motor and time to readiness for surgery.
• Trainee self-efficacy before and after block and pre-block anxiety using a 100-mm anchored scale.
• Patient experience using a 100-mm anchored scale. Pain, paraesthesia experienced, multiple attempts, sites.

WORKPLAN WP3 DETERMINE THE METHODOLOGICAL APPROACH TO TRAINING THAT BEST ENHANCES CLINICAL PERFORMANCE BEHAVIOUR DURING UGRA

Milestone 3.1 Train and video-record nerve block skills of trainees on soft embalmed Thiel cadaver.
Milestone 3.2 Test trainees by conducting a clinical RCT

In order to achieve Milestone 3.1, we will:
Collect baseline data:
• Trainee characteristics
• Trainee baseline testing of visuo-spatial ability and psychomotor ability.

Deliver standard teaching that reflects delivery at UGRA courses
• Twenty minute lecture on the conduct of interscalene block, highlighting all the necessary steps to perform and errors to avoid, before and during the block.
• Trainee ultrasound scanning of a volunteer for 20 min.
Needle practice on a blue plastic phantom with embedded tendon for 20 min.
•
Randomly allocate trainees, to one of two methods of training on the soft embalmed Thiel

cadaver – standard training or mastery learning
All participants will wear wireless eye tracking spectacles and have performance videoed by two fixed cameras, one focused on the transducer and the other further back focused on the screen and transducer. Procedures will be video recorded at 20, 40 and 60 min. Trainees allocated to the standard training group will conduct blocks repeatedly for 60 minutes whereas those allocated to the mastery learning group will conduct blocks repeatedly in a dedicated practice environment with feedback until a predefined level of proficiency is obtained, irrespective of time taken.

In order to achieve Milestone 3.2 we will:
Assess clinical performance:
Trainees will conduct clinical interscalene nerve block in Perth Royal Infirmary or Stracathro Hospital, NHS Tayside. The NHS Tayside Human Resources department will issue clinical access contracts on receipt of evidence of employment, GMC registration, defence union payment, and health checks. Clinical blocks will be performed on patients, 2 days and 6 weeks after training. All participants will wear wireless eye tracking spectacles and have performance videoed by two fixed cameras, one focused on the transducer and the other further back focused on the screen and transducer.

Measure the primary end point - the number of steps and errors assessed

Measure secondary end-points:
• Number of eye gaze fixations and eye glances conducting clinical interscalene block
• 9-point validated global rating scale (GRS) for summative assessment
• Quality of anaesthesia (preoperative and hourly recovery room pain scores at rest and movement using a 100-mm visual analogue pain scale; onset and distribution of sensory and motor and time to readiness for surgery.
• Trainee self-efficacy before and after block and pre-block anxiety using a 100-mm anchored scale.
• Patient experience using a 100mm anchored scale. Pain, paraesthesia experienced, multiple attempts, sites.

Workplan WP4
Milestone 4.1 Assess video recordings
Milestone 4.2 Conduct health economic analysis

In order to achieve Milestone 4.1 we will:
Recruit 16 regional anaesthetists as video raters, and ask them attend a formal training course, one in Scotland, the other in England. All steps and errors will be demonstrated on training videos, and raters tested. Reliable training will be defined as 80% agreement on testing of randomly selected pairs. Anaesthetist study investigators at the Thiel cadaver facility will remain separate from expert anaesthetic video raters.

We will conduct a cost-benefit analysis to compare the costs of the intervention against an estimate of the reduction in hospitalisation costs resulting from the reduced error rate. For the costs, estimates will be made of the costs of the time and manpower costs of training specialists to proficiency benchmarks in UGRA, and the cost of provision of nationwide simulator training. For the benefits, the costs of typical hospital stays due to a set of potential complications will be calculated, and the estimate of the reduction in the probability of error arising from the main study will be used to estimate the potential economic impact of the intervention in reducing hospital stays. In undertaking this pilot economic analysis we will explore the data availability and data collection requirements for estimating both the costs and the benefits. This will

directly inform the designing of a future full health economic analysis in a larger multi-institution study. Health economic evaluation of: time, cost and manpower

Intervention Type
Procedure/Surgery

Primary outcome measure
Step & error metrics measured using analysis of videos of anaesthetist's performance of interscalene block by independent, trained raters 1 week and 6 weeks after training.

Secondary outcome measures
1. The number of eye gaze fixations and the number of glances are measured using eye tracking glasses at the end of cadaver and training and at the end of clinical testing 1 week and 6 weeks after training
2. A nine-point validated global rating scale (GRS) for summative assessment is measured at the end of clinical testing 1 week and 6 weeks after training
3. Quality of anaesthesia (using preoperative and hourly recovery room pain scores at rest and movement using a 100-mm visual analogue pain scale; onset and distribution of sensory and motor and time to readiness for surgery) is measured during clinical testing 1 week and 6 weeks after training
4. Patient experience using a 100-mm anchored scale for pain and paraesthesia experienced is measured during clinical testing 1 week and 6 weeks after training
5. Technical difficulty measured as the number of multiple needle insertions and skin puncture sites is measured during clinical testing 1 week and 6 weeks after training
6. Trainee self-efficacy and mood is measured using a 100-mm anchored scale before and after training blocks on the soft embalmed cadaver
7. Number of steps and errors metrics is measured on videos of soft cadaver interscalene nerve block by independent, trained raters 1 week and 6 weeks after training
8. Health economic time, cost and manpower implications for training specialists to proficiency benchmarks; and cost of provision of nationwide simulator training against reduced complications is measured at the end of clinical testing

Overall study start date
01/09/2017

Completion date
30/11/2020

Eligibility

Key inclusion criteria
All anaesthetic trainees in Scotland

Participant type(s)
Health professional

Age group
Adult

Sex

Both

Target number of participants
72

Total final enrolment
11

Key exclusion criteria
Inability to tolerate eye tracking glasses

Date of first enrolment
01/06/2018

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
NHS Tayside

Sponsor details
TAyside medical Science Centre
TASC Research & Development Office
Ninewells Hospital & Medical School
Residency Block, Level 3
George Pirie Way
Dundee, United Kingdom
DD1 9SY
Dundee

United Kingdom
DD1 9SY
+44 (0) 1382 383900
tasctayside@nhs.net

Sponsor type
Research organisation

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Not defined

Funder Name
National Institute of Academic Anaesthesia (United Kingdom)

Results and Publications

Publication and dissemination plan
Three intended publications
1. Confirmation of reliable, objective metrics that best reflect performance on soft embalmed cadaver simulator
2. Type of simulator that best enhances clinical performance behaviour during ultrasound guided regional anaesthesia
3. Best educational methodological approach to simulator training that enhances clinical performance.

Intention to publish date
30/11/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date. The investigators are in discussion with the University as to how best to do this in line with current and future regulations

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		30/04/2018	01/04/2019	No	Yes
Participant information sheet		30/04/2018	01/04/2019	No	Yes