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A2B – a study investigating the effect of different types of sedation on the length of time critically ill patients require ventilation in intensive care

Submission date
23/10/2018

Recruitment status
No longer recruiting

Registration date
25/10/2018

Overall study status
Completed

Last Edited
04/07/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many patients in intensive care (ICU) need help to breathe on a breathing machine and need pain killers and sedatives to keep them comfortable and pain-free. However, keeping patients too deeply sedated can make their ICU stay longer, can cause ICU confusion (delirium), and afterwards may cause distressing memories. Ideally, we want to keep patients less sedated, but it is difficult to get the balance of sedation and comfort right. For sedation, most ICUs use a drug called propofol that is good at reducing anxiety and making people sleepy, but is not a painkiller, so additional painkillers are needed. There are two other drugs used less often called alpha-2 agonists that have both sedative and painkilling actions, which may make it easier for patients to be more awake and comfortable on the ventilator. The two drugs are called clonidine and dexmedetomidine. The aim of this study is to find out whether starting an alpha2-agonist drug early in ICU, and using this instead of propofol as much as possible, can help keep patients more lightly sedated but still comfortable, and whether patients spend less time on the ventilator with these drugs. The researchers also want to find out how safe they are, if they can improve important outcomes during ICU stay (like delirium, comfort, and safety) and during recovery (like bad memories, anxiety, and depression), and if they are value for money.

Who can participate?
Patients aged 18 years and over who need to be on a ventilator for at least 2 days

What does the study involve?
Patients are randomly allocated to one of three groups. One group continues to receive propofol, one group receives dexmedetomidine, and one group receives clonidine. All patients receive extra pain relief if needed, and patients in the dexmedetomidine and clonidine groups continue to receive propofol if they need this in addition. Nurses and doctors alter the doses of sedation drugs to try and reduce or stop them, but always aiming to have patients lightly sedated and comfortable. The study assesses whether patients on dexmedetomidine or clonidine come off the ventilator quicker than those just on propofol, and looks at whether

there is a difference between the groups in the number of people who experience delirium in ICU, how comfortable people are, and whether participants' memories of being in the ICU differed. Participants are followed up for 180 days afterwards to see if there are differences in the after-effects of being ill in ICU between the groups. Participants complete questionnaires to assess their memories of the ICU experience at 90 days after entering the trial. At 180 days, they also complete questionnaires about their quality of life or if they suffer from anxiety, depression or stress. Value for money is important because the costs of clonidine, dexmedetomidine, and propofol are quite different. Clonidine, in particular, is relatively inexpensive. ICU nurses' and doctors' views are collected on how easy or difficult it was to adjust and use the drugs, to provide valuable practical information that can be shared with other ICUs, particularly if alpha2-agonists are found to be better and other ICUs want to start using them. [Note that for participants recruited in the final months of trial recruitment, the 90- and 180-day follow-up will be truncated and not collected. This was agreed with the TSC and funder to reduce trial costs and enable trial completion.]

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in the trial but it may help to improve outcomes for patients requiring treatment with a ventilator in ICU in the future. As the sedative drugs being used in this study are commonly used drugs, the potential risk to patients on the trial is similar to the potential risk of patients on ventilation and sedative therapy who are not in the trial.

Where is the study run from?
The University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
April 2018 to July 2024

Who is funding the study?
The NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
1. Sian Irvine, sian.irvine@ed.ac.uk
2. Prof. Timothy Walsh, timothy.walsh@ed.ac.uk

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2018-001650-98

Integrated Research Application System (IRAS)
243640

ClinicalTrials.gov (NCT)
NCT03653832

Protocol serial number
HTA 16/93/01, IRAS 243640

Study information

Scientific Title
Alpha 2 agonists for sedation to produce better outcomes from critical illness (A2B Trial): a randomised, parallel-group, allocation concealed, controlled, open, Phase III pragmatic clinical and cost-effectiveness trial with internal pilot

Acronym
A2B

Study objectives

The primary hypothesis is that sedation with α2-agonists decreases the time to extubation in adult mechanically ventilated ICU patients compared with usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/08/2018, Scotland A Research Ethics Committee (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0)131 465 5680; manx.neill@nhslothian.scot.nhs.uk), ref: 18/SS/0085

Study design
Randomized, parallel-group, allocation concealed, controlled, open-label, phase III, pragmatic, clinical and cost-effectiveness multi-centre trial with an internal pilot

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Critically ill intensive care patients receiving mechanical ventilation

Interventions
Patients will be allocated in a 1:1:1 ratio to the three trial groups detailed below using permuted blocks (randomly arranged sizes of 3, 6, 9, 12) stratified by centre using a remote web-based randomisation system:
1. Dexmedetomidine - dosing regimen - the regimen will follow the manufacturer's guidance and regimens used in previous trials. Dexmedetomidine will be up and down titrated against sedation targets set by clinical staff and reviewed at regular intervals, and documented at least daily. No loading dose will be administered. The starting dose will be 0.7 µg/kg/hour titrated to a maximum dose 1.4 µg/kg/hour. Lower starting doses will be used at clinical discretion for patients with cardiovascular instability.
2. Clonidine – dosing regimen is similar to that currently used in many UK ICUs as part of routine 'off label' practice. Clonidine will be up and down titrated against sedation targets set by clinical staff and reviewed at regular intervals, and at least daily. No loading dose will be administered. The starting dose will be 1.0 µg/kg/hour titrated to a maximum dose of 2.0 µg/kg/hour.
3. Propofol (usual care) – dosing regimen - participants will continue to receive intravenous propofol according to current usual care. The sedation targets, weaning, and sedation discontinuation procedures will follow the same clinical targets as for the clonidine and dexmedetomidine groups.

Patients will commence intravenous infusion of open-label study drug according to a weight-based dose regimen as early as possible post randomisation, and within a maximum of 2 h. Bedside clinical staff will transition patients to achieve sedation with the allocated α2-agonist agent as quickly as clinically feasible and safe, to replicate the way these drugs would be used in routine practice. Additional opiate will be used for analgesia using clinical judgement.

The intervention period will continue until the patient is weaned from MV and sedation in the ICU. The timing of discontinuation of sedative agents will be at the discretion of the clinical team.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Dexmedetomidine, clonidine, propofol

Primary outcome(s)
Time to successful extubation post-randomisation (hours). A successful first extubation from mechanical ventilation will be defined as follows:
1. From endotracheal extubation: time of first extubation that is followed by 48 hours of spontaneous breathing
2. From tracheostomy: time of extubation will be defined as the first time a patient receives support not exceeding 5 cmH2O CPAP with less or equal to pressure support ventilation of 5cmH2O for a continuous period of 48 hours

Added 30/07/2024:
3. From non-invasive mechanical ventilation (NIV): time of extubation will be the start time of the first period during which a patient receives support not exceeding 5 cmH2O CPAP via mask /hood for a continuous period of 48 hours. NIV patients receiving any pressure-supported breaths will not be considered to be spontaneously breathing unassisted.

Timepoints: Time of randomisation and time of successful extubation

Key secondary outcome(s))
Current secondary outcome measures as of 09/03/2022:
1. Length of ICU stay (number of days). ICU status will be recorded daily from the date of randomisation until the date of ICU discharge, or 180 days, whichever comes first
2. Delirium during ICU stay, assessed twice daily during ICU stay using the Confusion-Agitation method for ICU (CAM-ICU). Delirium will be assessed from the date of randomisation until the date of ICU discharge, or 28 days, whichever comes first
3. Duration of delirium during ICU stay. Delirium will be assessed twice daily during ICU stay using the Confusion-Agitation method for ICU (CAM-ICU). Delirium will be assessed from the date of randomisation until the date of ICU discharge, or 28 days, whichever comes first
4. Sedation quality measured by Richmond Agitation and Sedation Scale (RASS) 4 hourly during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
5. Sedation quality measured by Sedation Quality Assessment Tool (SQAT) daily during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
6. Analgesia quality measured by Richmond Agitation and Sedation Scale (RASS) 4 hourly during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
7. Analgesia quality measured by Sedation Quality Assessment Tool (SQAT) daily during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
8. Number of hours to first optimum sedation as measured by a RASS score of -2 or greater. Level of sedation will be assessed 4 hourly during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first

9. Number of days to first optimum sedation as assessed by the Sedation Quality Assessment Tool (SQAT). Level of sedation will be assessed daily during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
10. Ability to communicate pain. Binary assessment by bedside nurse twice daily during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
11. Ability to co-operate with care. Binary assessment by bedside nurse twice daily during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
12. Relative/Partner/Friend (PerLR) assessment of wakefulness. Response to verbal question, assessed by a Relative/Partner/Friend daily during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
13. Relative/Partner/Friend (PerLR) assessment of patient comfort. Response to verbal question, assessed by a Relative/Partner/Friend daily during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
14. Relative/Partner/Friend (PerLR) assessment of patient communication. Response to verbal question, assessed by a Relative/Partner/Friend daily during the period of ventilation from the date of randomisation until the participant is successfully extubated, or 28 days, whichever comes first
15. Incidence of drug-related adverse events (bradycardia, hypotension, hypertension, cardiac arrhythmias, cardiac arrest) as documented in the medical records recorded daily from the date of randomisation until the date of documented successful extubation, or 28 days, whichever comes first
16. Incidence of mortality, as documented in the medical records from the date of randomisation until the date of the last follow-up visit at 180 days
17. Patient experience of ICU care measured by Intensive Care Experience Questionnaire at 90 days post ICU discharge
18. Occurrence of anxiety and depression measured by Hospital Anxiety and Depression Scale (HADS) questionnaire at 180 days post ICU discharge
19. Occurrence of post-traumatic stress measured by Impact of Events Scale-revised (IES-R) at 180 days post ICU discharge
20. Cognitive function assessed using the Montreal Cognitive Assessment Tool (Postal or Telephone) at 180 days post ICU discharge
21. Health-related quality of life (recalled) assessed by EuroQol tool (EQ-5D-5L) at 30 days post ICU discharge - recalled prior to hospital admission
22. Health-related quality of life (30 day) assessed by EuroQol tool (EQ-5D-5L) at 30 days post ICU discharge
23. Health-related quality of life (90 day) assessed by EuroQol tool (EQ-5D-5L) at 90 days post ICU discharge
24. Health-related quality of life (180 day) assessed by EuroQol tool (EQ-5D-5L) at 180 days post ICU discharge

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1. Length of ICU stay (number of days). ICU status will be recorded daily from the date of randomisation until the date of ICU discharge, or 180 days, whichever comes first
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16. Incidence of mortality, as documented in the medical records from the date of randomisation until the date of the last follow-up visit at 180 days
17. Patient experience of ICU care, measured by Intensive Care Experience Questionnaire at 30 days post ICU discharge
18. Patient experience of ICU care measured by Intensive Care Experience Questionnaire at 90 days post ICU discharge
19. Occurrence of anxiety and depression measured by Hospital Anxiety and Depression Scale (HADS) questionnaire at 90 days post ICU discharge
20. Occurrence of anxiety and depression measured by Hospital Anxiety and Depression Scale (HADS) questionnaire at 180 days post ICU discharge
21. Occurrence of post-traumatic stress measured by Impact of Events Scale-revised (IES-R) at 90 days post ICU discharge
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180 days post ICU discharge
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24. Cognitive function assessed using the Montreal Cognitive Assessment Tool (Postal or Telephone) at 180 days post ICU discharge
25. Health-related quality of life (recalled) assessed by EuroQol tool (EQ-5D-5L) at 30 days post ICU discharge - recalled prior to hospital admission
26. Health-related quality of life (30 day) assessed by EuroQol tool (EQ-5D-5L) at 30 days post ICU discharge
27. Health-related quality of life (90 day) assessed by EuroQol tool (EQ-5D-5L) at 90 days post ICU discharge
28. Health-related quality of life (180 day) assessed by EuroQol tool (EQ-5D-5L) at 180 days post ICU discharge

Completion date
31/07/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 22/06/2020:
1. Patient requiring mechanical ventilation (MV) in an ICU
2. Aged 18 years or over
3. Within 48 h of first episode of MV in ICU
4. Requiring sedation with propofol
5. Expected to require a total of 48 hours of MV or more in ICU
6. Expected to require a further 24 hours of MV or more at the time of randomisation in the opinion of the responsible clinician

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Previous inclusion criteria:
1. Patient requiring mechanical ventilation (MV) in an ICU
2. Aged 18 or over
3. Within 48 hours of starting MV in an ICU
4. Requiring sedation with propofol
5. Expected to require a total of 48 hours of MV or more in ICU
6. Expected to require a further 24 hours of MV or more at the time of randomisation in the opinion of the responsible clinician

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1437

Key exclusion criteria
Current exclusion criteria as of 22/06/2020:
1. Acute brain injury (traumatic brain injury; intracranial haemorrhage; ischaemic brain injury from stroke or hypoperfusion)
2. Post-cardiac arrest (where there is clinical concern about hypoxic brain injury)
3. Status epilepticus
4. Continuous therapeutic neuromuscular paralysis at the time of screening or randomisation
5. Guillain-Barre Syndrome
6. Myasthenia gravis
7. Home ventilation
8. Fulminant hepatic failure
9. Patient not expected to survive 24 h by responsible clinician
10. Decision to provide only palliative or end-of-life care
11. Pregnancy
12. Known allergy to one of the study drugs
13. Untreated second or third degree heart block
14. Transferred from another Intensive Care Unit in which MV occurred for >6 h
15. Prisoners
16. Enrolled on another CTIMP
17. Previously enrolled on the A2B Trial
18. Patients with bradycardia: a heart rate of <50 bpm for a period of 60 min or longer since starting MV in the ICU

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1. Acute brain injury (traumatic brain injury; intracranial haemorrhage; ischaemic brain injury from stroke or hypoperfusion)
2. Post-cardiac arrest (where there is clinical concern about hypoxic brain injury)
3. Status epilepticus
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15. Prisoners
16. Enrolled on another CTIMP
17. Previously enrolled on the A2B Trial

Date of first enrolment

30/09/2018

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
NHS Lothian
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Study participating centre

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Sponsor information

Organisation
Academic and Clinical Central Office for Research and Development (ACCORD)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 30/07/2024:
The datasets generated during and/or analysed during the current study are/will be available

upon request from Prof. Tim Walsh (Timothy.Walsh@ed.ac.uk). The data will not be available until around August 2024. Consent was requested from patients to anonymously share their data with other researchers.

Current individual participant data (IPD) sharing statement as of 09/03/2022:
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Tim Walsh (Timothy.Walsh@ed.ac.uk). The data will not be available until around June 2023. Consent was requested from patients to anonymously share their data with other researchers.

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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/05/2025	04/07/2025	Yes	No
Protocol article		10/12/2023	30/07/2024	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 7.0	25/04/2023	30/07/2024	No	No
Statistical Analysis Plan		27/03/2024	30/07/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes