Intensive Care Unit Randomised Trial Comparing Two Approaches to Oxygen Therapy

Site Initiation Visit

IRAS ID: 288506  
REC Ref: 20/SC/0423  
Funding: NIHR HTA (130508)

NIHR CPMS ID: 46926  
ISRCTN Registry: ISRCTN13384956  
Sponsor: ICNARC (01/10/20)

Chief Investigators: Prof Daniel Martin & Mr Paul Mouncey
Agenda

- Background and trial design
- Governance
- Patient flow
- Support/resources
Agenda

- Background and trial design
- Governance
- Patient flow
- Support/resources
Background

- Oxygen is the commonest drug administered to patients on ICU
- Approx. 55,000 patients per year receive mechanical ventilation with supplemental oxygen in NHS ICUs
- Whilst severe hypoxaemia can be harmful, the administration of excessive oxygen may also be harmful
- Traditionally we have given more (rather than less) oxygen to avoid hypoxaemia
- We do not know what the optimal amount of oxygen to give to patients is, or what their optimal oxygenation level should be
HARM

Hypoxaemia

Hyperoxaemia

ARTERIAL OXYGENATION

Martin & Grocott. Crit Care Med 2013
Background

- High concentration oxygen is thought to be harmful to the lungs and induce an inflammatory response.

- Retrospective studies have linked hyperoxaemia to worse clinical outcomes.

- *Conservative oxygen therapy* (or permissive hypoxaemia) is the purposeful administration of less oxygen than usual to patients, to achieve lower than normal arterial oxygenation levels ($\text{SpO}_2 / \text{PaO}_2$).
Background

- A number of randomised trials have sought to evaluate the role of conservative oxygen therapy in reducing mortality

<table>
<thead>
<tr>
<th>Study</th>
<th>Conservative</th>
<th>Liberal</th>
<th>Risk Ratio with 95% CI</th>
<th>Weight (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schjøring et al 2021</td>
<td>611/1441 (42.9)</td>
<td>613/1447 (42.4)</td>
<td>1.01 [0.93, 1.10]</td>
<td>28.62</td>
</tr>
<tr>
<td>Barrot et al 2020</td>
<td>44/99 (44.4)</td>
<td>31/102 (30.4)</td>
<td>1.46 [1.01, 2.11]</td>
<td>11.38</td>
</tr>
<tr>
<td>Mackle et al 2019</td>
<td>166/479 (34.7)</td>
<td>156/480 (32.5)</td>
<td>1.07 [0.89, 1.27]</td>
<td>22.16</td>
</tr>
<tr>
<td>Asfar et al 2017</td>
<td>78/219 (35.6)</td>
<td>95/223 (42.6)</td>
<td>0.84 [0.66, 1.06]</td>
<td>18.27</td>
</tr>
<tr>
<td>Girardis et al 2016</td>
<td>58/235 (24.7)</td>
<td>80/243 (32.9)</td>
<td>0.75 [0.56, 1.00]</td>
<td>15.15</td>
</tr>
<tr>
<td>Panwar et al 2016</td>
<td>13/53 (24.5)</td>
<td>12/51 (23.5)</td>
<td>1.04 [0.53, 2.07]</td>
<td>4.43</td>
</tr>
</tbody>
</table>

Overall

Heterogeneity: $I^2 = 63.23\%$, $H^2 = 2.72$

Test of $\theta = 0$: $Q(5) = 10.84$, $p = 0.05$

Test of $\theta = 0$: $z = -0.17$, $p = 0.86$

Random-effects REML model

- To date the evidence is equivocal
Background

- Largest trial to date (HOT-ICU) compared PaO$_2$s of 8.0 and 12.0 in 2928 patients with hypoxaemic respiratory failure and found no difference in 90 day all cause mortality

- We have conducted a study to evaluate the feasibility of using conservative oxygen therapy in an NHS setting

- Conservative oxygen therapy has never been evaluated in mechanically ventilated patients admitted to ICU in an NHS setting
Aim
- To evaluate the clinical and cost-effectiveness of conservative oxygen therapy for mechanically ventilated adult patients in ICU

Research question
- **Population**: In adults receiving mechanical ventilation and supplemental oxygen in ICU
- **Intervention**: is conservative oxygen therapy superior to
- **Comparator**: usual oxygen therapy
- **Outcome**: in terms of 90-day all-cause mortality?
Trial design

- Large-scale, multi-centre, data-enabled, registry-embedded, RCT with an internal pilot and integrated economic evaluation
- 16,500 patients (randomised 1:1)
  - Provides 90% power to detect a 2.5% absolute risk reduction in 90-day mortality (from 37% to 34.5%)
  - Recruited from approx. 100 ICUs
  - 24-month recruitment period

- Internal pilot runs May - October 2021
  - Progression criteria: sites open, recruitment rate, adherence and separation between groups
Feasibility of recruitment

• Many eligible patients!
  o Median of 17 eligible patients per ICU/month
  o 86% should see at least 8 eligible patients/month
Outcomes

• Primary
  o All-cause mortality at 90 days (clinical)
  o Incremental costs, quality-adjusted life years and net monetary benefit at 90 days (economic)

• Secondary
  o ICU and acute hospital mortality
  o 60-day and 1-year mortality
  o Duration of ICU and acute hospital stay
  o Health-related Quality of Life at 90 days
  o Resource use and costs at 90 days
  o Estimated lifetime incremental cost-effectiveness
Agenda

- Background and trial design
- Governance
- Patient flow
- Support/resources
Central governance

- Funded by NIHR Health Technology Assessment Programme
- HRA/HCRW Approval and REC favourable ethical opinion in place
- Adopted onto NIHR Portfolio
- Sponsored by ICNARC and managed by ICNARC CTU

- Oversight by:
  - Trial Management Group
  - Independently-chaired Trial Steering Committee
  - Independent Data Monitoring and Ethics Committee
    - Interim analyses at 4,500 and 10,000 patients
Local governance

- Site research team led by PI
  - NIHR Associate PI scheme

- Local information pack and ISF documents provided electronically
Agenda

• Background and trial design
• Governance
• Patient flow
• Support/resources
Patient flow

1. Screening

2. Randomisation

- Conversative oxygen therapy
- Usual oxygen therapy

3. Consent

4. Follow-up

Safety monitoring
Data collection
Patient flow

Screening

Randomisation

Conversative oxygen therapy

Usual oxygen therapy

Consent

Follow-up

Safety monitoring

Data collection
Eligibility

- **Inclusion criteria**
  - Aged ≥18 years
  - Receiving invasive mechanical ventilation following an unplanned ICU admission **OR** invasive mechanical ventilation started in the ICU
  - FiO\(_2\) >0.21 at time of randomisation

- **Exclusion criteria**
  - Previously randomised to UK-ROX in last 90 days
  - Currently receiving ECMO
  - The treating clinician considers that one study treatment arm is either indicated or contraindicated

- **Patients must be randomised within 12 hours of starting invasive mechanical ventilation in ICU**
  - Must be the first time the patient received invasive mechanical ventilation in ICU during this hospital stay.
Screening & randomising

- Screen all patients receiving invasive mechanical ventilation in ICU
- Aiming to embed screening within routine clinical practice
- Timely randomisation essential *(12-hour window)*
- Simple trial procedures
- Coverage for out-of-hours randomisations
  - clinical staff training and engagement

See SOP 003
### Screening and Enrolment Log

- **Screening Log**
  - Record patients meeting the mechanical ventilation inclusion criteria
  - Each row represents a patient admission
  - Section A: Enter basic patient details and select ‘Screening outcome’

#### Screening Log - Record all patients receiving MV following unplanned ICU admission OR where MV started in the ICU

Remove Column A (Local identifier) prior to submission to ICNARC

<table>
<thead>
<tr>
<th>Local identifier (remove prior to submission to ICNARC)</th>
<th>CMP Number</th>
<th>Date started MV (dd/mm/yyyy)</th>
<th>Aged ≥18 years? (Y/N)</th>
<th>FiO2 &gt; 0.21 during first 12 hours of MV? (Y/N)</th>
<th>Screening outcome</th>
<th>Trial Number</th>
<th>Reason not randomised (select and explain in comments)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Randomised (go to section B)**
- Met exclusion - previously randomised in last 90 days
- Met exclusion - one treatment arm indicated/contraindicated (explain in comments)
- Met exclusion - on ECMO
- Eligible not randomised (go to section C)
- Eligibility unknown
Screening and Enrolment Log

- **Enrolment Log**
  - Second tab helps you keep track of actions required for each patient

**UK-ROX Enrolment Log**

<table>
<thead>
<tr>
<th>Consent/opinion</th>
<th>Data collection</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Number</td>
<td>Consultee opinion sought?</td>
<td>Patient consent sought?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Submit excel file regularly to ICNARC CTU
  - e.g. initially fortnightly, then monthly
  - email to [uk-rox@icnarc.org](mailto:uk-rox@icnarc.org)

*Do not submit any identifiable information*

See SOP 003
# Screening Tool (optional)

## Screening Tool

<table>
<thead>
<tr>
<th>Hospital number</th>
<th>Aged ≥ 18 years? (Y/N)</th>
<th>Datetime started invasive mechanical ventilation</th>
<th>Screened within 12 hours of starting invasive mechanical ventilation? (Y/N)</th>
<th>Eligibility confirmed by</th>
<th>If randomised</th>
<th>If not randomised</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Name of staff</td>
<td>Trial Number</td>
<td>Provide reason</td>
</tr>
</tbody>
</table>

If all Yes, then review exclusion criteria and complete Randomisation Form if all eligibility criteria are met.

### Exclusion criteria
- Previously randomised into UK-ROX in the last 90 days
- Currently receiving ECMO
- The treating clinician considers that one study treatment arm is either indicated or contraindicated

### Unsure if a patient is eligible? Contact:
- Your Principal Investigator or research team for assistance
- ICNARC CTU: 020 7269 9277 or uk.rox@icnarc.org

[See SOP 003](#)
Co-enrolment

• Observational studies (including those collecting samples)
  o Permitted without prior agreement

• Interventional studies
  o Decided case-by-case
  o Agreement in place with:
    ▪ A2B
    ▪ EFFORT
    ▪ REMAP-CAP
    ▪ VITDALIZE UK
    ▪ VACIRiSS
    ▪ STRESS-L
    ▪ ADAPT-SEPSIS
    ▪ RECOVERY
    ▪ BLING III
Patient flow

Screening

Randomisation

Conversative oxygen therapy

Usual oxygen therapy

Consent

Follow-up

Safety monitoring

Data collection

www.icnarc.org
Patient flow

Screening

Randomisation

Conversative oxygen therapy

Usual oxygen therapy

Consent

Follow-up

Safety monitoring

Data collection

www.icnarc.org
Randomisation

- Dedicated 24/7 randomisation service
- Telephone randomisation
  - Dial: 020 3384 6368
  - Study number: 7102
  - Your investigator number will be assigned
- Web randomisation
  - Email uk-rox@icnarc.org to request an account
  - Can use generic/group or individual email addresses

- Trial training required to randomise (Training Log)
  - GCP training not required
How to randomise

Details required by randomisation service
- Confirmation of eligibility
- Key baseline data

Confirmation of randomisation

Sign off by trained staff member
Randomisation

- Auto-generated randomisation notification emails
  - Email ukrox@icnarc.org to add recipients

- Errors
  - Once randomised, patient is in trial and included in analysis - consent and data collection must be carried out per protocol
  - If patient accidentally randomised twice, use first randomisation
    - Check email notification if unsure of the status of a randomisation (or contact local team/ICNARC CTU)
    - Do not re-use the second randomisation details
Patient flow

- Screening
  - Randomisation
    - Conversative oxygen therapy
    - Usual oxygen therapy
      - Consent
        - Follow-up

Safety monitoring
Data collection
Patient flow

- Screening
- Randomisation
- Consent
- Follow-up

- Conversative oxygen therapy
- Usual oxygen therapy

Safety monitoring
Data collection
Intervention period

- Begins immediately following randomisation

- The interventions remain the same once a patient is extubated, regardless of the modality by which they receive oxygen therapy

- The interventions should be continued until ICU discharge or 90 days after randomisation, whichever is sooner
  - If readmitted to ICU within the 90 days, the intervention should be recommenced
Conservative oxygen therapy

- The lowest concentration of oxygen possible should be administered to maintain the patient’s SpO₂ at **90(±2)%**
- For patients receiving oxygen, SpO₂ should not rise above **92%** (monitor alarm set to 93%)
- SpO₂ should not fall lower than **88%**
Conservative oxygen therapy

CONSERVATIVE OXYGEN THERAPY
When receiving oxygen

Set upper alarm to prevent an SpO₂ > 92%

Reduce FiO₂ until SpO₂ is 90%

Set lower alarm to prevent an SpO₂ < 88%

* If SpO₂ is > 92% despite an FiO₂ of 0.21, the upper alarm will need to be removed
Conservative oxygen therapy

• When a patient is not receiving additional oxygen, a higher SpO$_2$ alarm should not be set

• Continue to monitor SpO$_2$

• If additional oxygen is required again, revert to the algorithm for patients receiving oxygen
Protocol deviation

- Trigger to identify potential deviations:
  - where $\text{SpO}_2$ remains above 92% for three consecutive hours and $\text{FiO}_2$ is not reduced or at the lower limit of 0.21
- Sites contacted to find out reasons why oxygen was not reduced
  - Important that reasons are documented locally
Training

- Ensure staff are aware of trial and that they may be managing intervention group patients
  - Including temporary/bank/agency staff
- Ensure bedside staff are confident in titrating $\text{FiO}_2$ to an $\text{SpO}_2$ target of 90 ($\pm 2$)%
- Ensure alarms are set appropriately and $\text{SpO}_2$ targets handed over to subsequent shifts
- Discussion point at ward rounds
- Use of electronic patient record to monitor $\text{SpO}_2$ values and prompt titration of $\text{FiO}_2$?
- Use stickers/labels for intervention group patients
Patient flow

- Screening
- Randomisation
- Conversative oxygen therapy
- Usual oxygen therapy
- Consent
- Follow-up

Safety monitoring
Data collection
Patient flow

- Screening
- Randomisation
- Conversative oxygen therapy
- Usual oxygen therapy
- Consent
- Follow-up

- Safety monitoring
- Data collection
Usual oxygen therapy

- Defined by local practice, determined by treating clinician
- Chosen SpO₂ targets should be documented daily
- A lower limit alarm can be set at the discretion of the treating clinician
- An upper SpO₂ alarm must not be used
- Research staff should avoid interactions that may influence usual care
Patient flow

Screening

Randomisation

Conversative oxygen therapy

Usual oxygen therapy

Consent

Follow-up

Safety monitoring

Data collection
Research Without Prior Consent

- Patients will lack capacity at time of randomisation
- Emergency waiver of consent granted by REC (Mental Capacity Act)

- After randomisation - once patient’s medical situation is considered no longer an emergency, the consent procedures should begin
  - Consent sought after randomisation by GCP-trained team member
  - Expected to be within 24-48 hours of randomisation

- Posters and leaflets publicly available
Consent procedures

Patient confirmed eligible

See SOP 007
In rare situation where patient has capacity:
seek verbal/other non-written consent
to randomise if appropriate,
otherwise consent is deferred
Consent procedures

Patient confirmed eligible → Randomisation

- Once medical situation is no longer an emergency (around 24-48 hours after randomisation)
  - If patient has capacity: Approach patient for consent
  - If patient lacks capacity:
    - If patient lacks capacity and there is no personal consultee OR if patient has died:
      - Approach Nominated Consultee for opinion
    - Approach Personal Consultee for opinion (in person/telephone)

Seek verbal/other non-written consent, if appropriate

See SOP 007
Personal Consultee opinion

- If patient lacks capacity, approach Personal Consultee
  - Relative/close friend - not restricted to next of kin
- Consultee advises on patient’s likely wishes/feelings regarding participation in the trial
- Approach:
  - In person (preferred)
    - Give Personal Consultee Information Sheet and use Opinion Form
  - Telephone (if unable to visit)
    - Offer to send Personal Consultee Information Sheet via email or post
    - Complete Telephone Personal Consultee Opinion Form
    - Must be witnessed

See SOP 007
Nominated Consultee opinion

- Approach Nominated Consultee if:
  - Patient lacks capacity and no personal consultee is available
  - Patient has died
- Nominated Consultee can include:
  - Doctor independent of the trial (not on Delegation/Training Log)
  - Independent Mental Capacity Advocate
- Purpose
  - to advise on patient’s likely wishes/feelings regarding participating in the trial
  - to reduce stress on grieving relatives

See SOP 007
Patient informed consent

- Upon recovery, patient should be approached directly
  - Give Patient Information Sheet
  - Approach with Consent Form
    - Explain consent options

- If patient wishes to have more time or is discharged, approach by telephone/post after discharge
  - Complete Telephone Consent Form
  - Must be witnessed

- Patient’s decision is final
Explaining the trial

- Information should be clear, concise and not medicalised
- Explain:
  - why we are doing the trial
  - why consent cannot be sought in emergency situations
  - explain oxygen therapy and ventilators in easy to understand terms
- Allow time to think about the trial, discuss with friends/family and ask questions
Completion of consent/opinion forms

- Signing indicates agreement with points 1-5
- Points 6-7 (follow-up and anonymised data sharing) should be initialled if in agreement
  - Optional but should be encouraged
- Patient/consultee completes first, then person seeking consent checks form is completed correctly and countersigns in their presence
- If patient unable to physically sign the form, and independent witness may sign on their behalf
- A copy given to the patient/consultee, a copy for medical notes and original stored in ISF

See SOP 007
Consent procedures

• Documents:
  o Patient Information Sheet
  o Personal Consultee Information Sheet
  o Nominated Consultee Information Sheet
  o Information Leaflet
  o Consent Form
  o Telephone Consent Form
  o Postal Consent Form
  o Personal Consultee Opinion Form
  o Telephone Personal Consultee Opinion Form
  o Nominated Consultee Opinion Form
Refusals and Withdrawals

- If patient/consultee declines or withdraws consent, clarify which aspects they are declining/withdrawing from
  - Total vs. partial - may be willing to allow continued data collection (must be documented)
  - Not obliged to provide a reason

- Data on events occurring up to refusal/withdrawal retained in trial, unless patient/consultee requests otherwise
Patient flow

Screening → Randomisation

Conversative oxygen therapy → Consent → Follow-up

Usual oxygen therapy → Consent → Follow-up

Safety monitoring → Data collection
Patient flow

Screening

Randomisation

Conversative oxygen therapy

Usual oxygen therapy

Consent

Follow-up

www.icnarc.org

Site Initiation Visit
Safety monitoring

- Monitor safety between randomisation and ICU discharge or 90 days (whichever comes first)*
- Serious Adverse Events (SAEs) reported to ICNARC CTU:

<table>
<thead>
<tr>
<th>Expected Events</th>
<th>Unexpected Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Report all occurrences assessed as ‘severe’ or ‘life-threatening’ (SAEs):</td>
<td>• Report only if considered to have reasonably occurred as a consequence of oxygen therapy (usual or conservative)</td>
</tr>
<tr>
<td>• Sinus tachycardia</td>
<td>• Not events that are part of the natural primary disease process or expected complications of critical illness (e.g. multi-organ failure)</td>
</tr>
<tr>
<td>• Supraventricular tachycardia</td>
<td></td>
</tr>
<tr>
<td>• Atrial fibrillation</td>
<td></td>
</tr>
<tr>
<td>• Myocardial ischaemia/infarction</td>
<td></td>
</tr>
<tr>
<td>• Mesenteric ischaemia</td>
<td></td>
</tr>
</tbody>
</table>

*if readmitted to ICU within 90 days, safety monitoring recommences
Safety monitoring

- Submit SAE Report Form to uk-rox@icnarc.org
  - within 24 hours of site team becoming aware of the event
- Unexpected and at least possibly related (to usual/conservative oxygen therapy) events will be reported to the REC
  - Take extra care when completing ‘SAE Assessment’ section

<table>
<thead>
<tr>
<th>Relationship to event</th>
<th>Expectedness</th>
<th>SpO₂ action taken</th>
<th>Oxygen action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = None</td>
<td>1 = Expected</td>
<td>0 = None</td>
<td>0 = None</td>
</tr>
<tr>
<td>1 = Unlikely</td>
<td>2 = Not expected</td>
<td>1 = SpO₂ target increased</td>
<td>1 = Oxygen increased</td>
</tr>
<tr>
<td>2 = Possibly</td>
<td>3 = Definitely</td>
<td>2 = SpO₂ target decreased</td>
<td>2 = Oxygen decreased</td>
</tr>
<tr>
<td>3 = Probably</td>
<td></td>
<td></td>
<td>3 = Oxygen treatment ceased</td>
</tr>
</tbody>
</table>

- Enter data onto MACRO database
  - Do not submit any identifiable information
Patient flow

Screening → Randomisation

Conversative oxygen therapy → Consent

Usual oxygen therapy → Consent

Follow-up
Patient flow

Screening

Randomisation

Conversative oxygen therapy

Usual oxygen therapy

Consent

Follow-up

Safety monitoring

Data collection
Data collection

- Basic data collection - all patients
- Enhanced data collection - 15% of patients

- Other data planned to be obtained from national sources
  - Case Mix Programme, NHS Digital, NHS Wales Informatics Service
Basic data collection

- Data to confirm the outcome of the consent procedures
- Patient identifiers for data linkage
Enhanced data collection

- To monitor protocol adherence and between-group separation
- Retrospective chart abstraction of hourly respiratory support status, SpO$_2$, FiO$_2$, PaO$_2$ and SaO$_2$ measurements up to day 10 in ICU
- n=2,500 - 15% of overall sample size
  - first 10 randomisations from each site + randomly sampled patients across sites, treatment groups and the course of the trial
    - Sites notified of retrospectively selected patients
Data entry

- All randomised patients added to MACRO database:
  - [https://ctu.icnarc.org/macro/](https://ctu.icnarc.org/macro/)
    - Submit Research Staff Contacts Form to uk-rox@icnarc.org (listing all who need an account)
    - Individual must be listed on Delegation Log

- Separate optional training sessions on data collection/entry available
90-day questionnaire follow-up (enhanced patients only)

- Questionnaires
  - EuroQol Health questionnaire (EQ-5D-5L)
  - Health services and resource use questionnaire

- Questionnaire posted to patient at time point
- Non-responders telephoned three weeks later to check if received

- If an inpatient at 90 days, site asked to approach patient to complete questionnaire in person
Agenda

• Background and trial design
• Governance
• Patient flow
• Support/resources
Support/resources

- Site Initiation Visits
- Site Zoom/Teams calls
- Routine Monitoring Visits (COVID-19 dependent)
- Regular recruitment updates
- Data collection training sessions
- Newsletters
- Posters
- Pocket cards
- Labels/stickers

...let us know if you have any other ideas!
Local resources

- Direct research costs from ICNARC
  - Start-up and first patient: £250
  - Each ‘enhanced data collection’ patient: £50
  - Each ‘basic data collection’ patient: £20
  - Close-down: £250

- Each invoice must quote a unique PO number, requested in advance from uk-rox@icnarc.org

- Adopted on NIHR Portfolio (46926)
Things we need from you

- Prior to site activation:
  - Commence local training and awareness raising
  - Local confirmation of capacity and capability
  - Signed Clinical Trial Site Agreement
  - Delegation Log
  - Research Staff Contacts Form
  - Confirm attendance at training
  - Confirm screening start date

- Before/following activation:
  - Protocol signature page signed by PI
  - PI CV and GCP certificate
  - ISF checklist
  - Screening and Enrolment Log (after first two weeks of screening)
Lead Investigators

- Daniel Martin (Chief Investigator)
- Paul Mouncey (Chief Investigator)
- Miriam Davey (Research Nurse)
- James Doidge (Senior Statistician)
- Roger Garrett (Patient representative)
- Doug Gould (Senior Researcher)
- Mike Grocott (Professor/Consultant)
- David Harrison (Head Statistician)
- Jo Jones (Senior Research Nurse)
- Ronan O’Driscoll (Consultant)
- Alvin Richards-Belle (Trial Manager)
- Kathy Rowan (CTU Director)
- Zia Sadique (Health Economist)
- Paul Young (Consultant)

ICNARC CTU team

- Alvin Richards-Belle (Trial Manager)
- Lorna Miller (Research Assistant)
- Stefan Sprinckmoller (Data Manager)
- Carly Au (Senior Data Manager)
- Alexina Mason (Trial Statistician)
- Doug Gould (Senior Researcher)
- Paul Mouncey (Head of Research)

uk-rox@icnarc.org
020 7269 9277
icnarc.org/Our-Research/Studies/UK-ROX

Site Initiation Visit
Thank you

- Any questions?

uk-rox@icnarc.org

020 7269 9277

icnarc.org/Our-Research/Studies/UK-ROX