

Comparison of an automated weaning programme and a standard clinical weaning protocol for weaning critically ill patients

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 14/06/2016	Condition category Respiratory	☐ 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
Dr Richard Beale

Contact details
Adult ICU
East Wing
St Thomas' Hospital
Lambeth Palace Road
London
United Kingdom
SE1 7EH
+44 (0)20 7188 3038
Richard.Beale@gstt.nhs.uk

Additional identifiers

Protocol serial number
N0013154743

Study information

Scientific Title

Comparison of an automated weaning programme and a standard clinical weaning protocol for weaning critically ill patients: a randomised controlled trial

Study objectives

Will the use of an automated weaning system shorten the duration of mechanical ventilation, and will this be associated with reduced ventilator-associated complications e.g. pneumonia, tracheostomy?

Ethics approval required

Old ethics approval format

Ethics approval(s)

St Thomas' Hospital Research Ethics Committee

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Process of weaning from mechanical ventilation

Interventions

This is a randomised controlled trial comparing the ICU's standard ventilator weaning protocol and the SmartCare automated weaning system. Patients who are assessed as likely to need mechanical ventilation for a period of 48 hours or more will be randomised to be weaned from mechanical ventilation using either the standard protocol or the automated weaning system. Weaning will be initiated when, in the opinion of the clinical team, the patient is sufficiently improved as to be able to tolerate a spontaneous mode of ventilation and has met defined gas exchange and ventilatory support criteria. Once in the weaning phase, weaning will proceed according to the manual or SmartCare algorithms but will be suspended if the patient's clinical condition deteriorates, and re-instituted once the patient has improved sufficiently for weaning to recommence.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Time from the initiation of weaning to successful separation of the patient from the ventilator, defined as no longer needing mechanical ventilation for a minimum period of 48 hours.

Key secondary outcome(s)

Added as of 10/12/2007:

1. Mortality (28-day, ICU and hospital, six-months)
2. Infectious complications (e.g. pneumonia, wound infection, abscesses)
3. APACHE II
4. Organ failure-free days
5. LOS in ICU
6. LOS in hospital (intervention until discharge)
7. Duration of antibiotic treatment (antibiotics days)
8. Duration of ventilation (ventilator days)
9. Duration of renal support

Completion date

30/06/2010

Eligibility

Key inclusion criteria

Added as of 10/12/2007:

Major entry criteria (suspected or proven infection, presence of a systemic response to the infection within the 48-hour period immediately preceding enrolment into the study, have or have had one or more sepsis-induced organ failures within the 48-hour period immediately preceding enrolment into the study).

1. Age ≥ 18 years
2. Acute Physiology and Chronic Health Evaluation II (APACHE II) score ≥ 10
3. Precipitating injury (surgery, trauma, hypovolemia, episode of infection or sepsis) occurred within the last 48 hours before Intensive Care Unit (ICU) entry
4. Expected Length Of Stay (LOS) in the ICU > 3 days
5. Indication for enteral nutrition for 5-10 days
6. Start of nutritional therapy with Intestamin or control supplement within 24 hours after inclusion criteria are fulfilled

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Under 18 years of age
2. Requirement for high doses of vasopressor
3. Body temperature greater than 39°C or less than 36°C

4. GCS = 12 without or with minimal sedation
5. 'Do Not Resuscitate' order or expected short term prognosis
6. Patients chronically ventilated at home with tracheostomy
7. Patients with primary neurological cause of ventilator dependence
8. Pregnancy
9. Prolonged cardiac arrest with poor neurological prognoses
10. Inability to obtain consent from patient or legal representative

Date of first enrolment

01/12/2004

Date of final enrolment

30/06/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Adult ICU

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Guy's and St. Thomas' NHS Foundation Trust (UK)

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Government

Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration