ISRCTN82559457 https://doi.org/10.1186/ISRCTN82559457

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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 14/06/2016	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/12/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

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
England

United Kingdom

Study participating centre
Adult ICU
London
United Kingdom
SE1 7EH

Sponsor information

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

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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.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

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