ISRCTN68144998 https://doi.org/10.1186/ISRCTN68144998

Permissive underfeeding versus target enteral feeding in adult critically ill patients

Submission date
12/05/2009

Recruitment status
No longer recruiting

Registration date
24/06/2009

Overall study status
Completed

Last Edited
15/04/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Yaseen Arabi MD, FCCP, FCCM

Contact details
Chairman, Intensive Care Department
Assistant Professor
College of Medicine
King Saud Bin Abdulaziz University for Health Sciences
King Abdulaziz Medical City
Riyadh
Saudi Arabia
11426
+966 (0)1 252 0088 ext. 18855
yaseenarabi@yahoo.com

Additional identifiers

Protocol serial number
RC08/040

Study information

Scientific Title

The impact of permissive underfeeding versus target enteral feeding on mortality and morbidity in adult critically ill patients: a multicentre randomised controlled trial

Study objectives
1. To assess the effect of permissive underfeeding versus target feeding intake on mortality and morbidity of critically ill patients
2. To assess the effect of low versus high caloric intake on the incidence of nosocomial infections

Due to an error made at the time of registration, the overall trial end date was showing as 01/09/2009. As of 02/11/2010 this has now been amended and the correct end date of 01/09/2013 has been added to the overall trial end date field below.

On 06/11/2014 the following changes were made to the trial record:
1. The target number of participants was changed from 862 to 892.
2. The overall trial end date was changed from 01/09/2013 to 30/12/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the National Guard Health Affairs, King Abdul Aziz Medical City, 08/04/2009, ref: IRBC/017/09

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Enteral feeding

Interventions
All patients admitted to ICU will be screened within first 48 hours for eligiliblity and all potential eligible candidates will be identified. Patients will be allocated to one of the two groups:
1. Permissive underfeeding group: intake targeting 40 - 60% of calculated caloric requirement
2. Target group: intake targeting 70 - 100% of calculated caloric requirement

The allocated diet (permissive underfeeding versus target feeding) will be undertaken for a maximum of 14 days on study feeding protocol or at ICU discharge (whichever is earlier). Upon discharge from the ICU, feeding and glucose control will be at the discretion of ward clinicians. If oral feeding is started and tolerated for more than 24 hours, a Do-Not-Resuscitate order has been written (after enrolment) or brain death is confirmed (after enrolment) the study will be stopped in these participants.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
90 day-all cause mortality: death before or at day 90 of enrolment

Key secondary outcome(s)
1. ICU mortality: death in the ICU during the same ICU admission
2. Hospital mortality: death in the hospital (in ICU or on floor) during the same hospital admission
3. 180-day mortality: death before or at day 180 of enrolment
4. Daily Sequential Organ Failure Assessment (SOFA) scores recorded on days 1, 3, 7, 14, 21 and 28

Completion date
30/12/2014

Eligibility

Key inclusion criteria
1. Receiving enteral feeding
2. Aged greater than or equal to 18 years, either sex
3. Expected to stay 48 hours or more in the ICU

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Terminal illness
2. Do not resuscitate (DNR) order (no code, no escalation) in the first 48 hours
3. Enteral feeding cannot be started within 48 hours of admission
4. Total parenteral nutrition (TPN)
5. Oral feeding
6. Previously enrolled in this study within the same hospital admission
7. Brain death within 48 hours of admission
8. Pregnancy
9. Post-liver transplant
10. Post cardiac arrest
11. Burn patients

12. Prisoners
13. Elderly subjects aged greater than 80 years
14. Patients on more than one ionotropic support at maximum dose

Date of first enrolment
01/06/2009

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
Bahrain

Canada

Germany

Saudi Arabia

United Arab Emirates

Study participating centre
King Saud Bin Abdulaziz University for Health Sciences
Riyadh
Saudi Arabia
11426

Sponsor information

Organisation
King Abdullah International Medical Research Center (KAIMRC) (Saudi Arabia)

ROR
https://ror.org/009p8zv69

Funder(s)

Funder type
Research organisation

Funder Name
King Abdullah International Medical Research Center (KAIMRC) (Saudi Arabia)

Funder Name
King Abdul Aziz Medical City (Saudi Arabia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/06/2015		Yes	No
Results article	results	20/12/2018		Yes	No
Results article	results	01/02/2019		Yes	No
Results article	results	01/02/2019	15/04/2020	Yes	No
Protocol article	protocol	12/10/2012		Yes	No