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

# Permissive underfeeding versus target enteral feeding in adult critically ill patients

**Submission date**
12/05/2009

**Registration date**
24/06/2009

**Last Edited**
15/04/2020

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### Study design
Multicentre randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure
90 day-all cause mortality: death before or at day 90 of enrolment

### Secondary outcome measures
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

### Overall study start date
01/06/2009

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
892

### 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)

### Sponsor details
National Guard Health Affairs
King Saud Bin Abdulaziz University for Health Sciences
King Abdulaziz Medical City
Riyadh
Saudi Arabia
11426
+966 (0)1 252 0088 ext. 16593
CLNresearch1@ngha.med.sa

### Sponsor type
Hospital/treatment centre

### Website
http://kaimrc.info/

### 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

### 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 12/10/2012 | | Yes | No |
| 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 |