

The role of ghrelin in acute versus prolonged critical illness

Submission date 20/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/05/2013	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
The role of ghrelin in acute versus prolonged critical illness: A single centre, observational trial

Study objectives

To investigate whether (impaired) endogenous ghrelin secretion plays a role in the impaired pulsatile GH secretion and action during prolonged critical illness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study protocol and consent forms were approved by the Institutional Review Board (IRB) of the Catholic University Leuven School of Medicine on the 10th of November 2006 (ref: ML2112).

Study design

Single-centre observational study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Critical illness

Interventions

The patients will be studied once on day 1-2 of ICU admission, and once on day 10-14 (if still in ICU). Blood sampling from patients and healthy volunteers will take place during the night from 21.00 h to 06.00 h every 20 minutes.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Concentrations of ghrelin and GH will be measured in each sample.

Key secondary outcome(s)

1. Information obtained from each patient at baseline
 - 1.1. Demographic
 - 1.2. Diagnostic
 - 1.3. Therapeutic
 - 1.4. Severity of illness (Acute Physiology and Chronic Health Evaluation [APACHE-II]) (Knaus W.A. et al. Critical Care Medicine, 1985, 13:818-829)
2. Evaluation of trends in organ dysfunction (Sepsis-related Organ Failure Assessment score [SOFA]) (Intensive Care Med. 1996,22:707-10)
3. At 06.00h, serum concentrations of the following will be measured:
 - 3.1. Insulin-like growth factor I (IGF-I)
 - 3.2. IGF-binding protein-1 (IGFBP-1)
 - 3.3. IGFBP-3
 - 3.4. The acid-labile subunit (ALS)

- 3.5. IGFBP-4
- 3.6. IGFBP-5
- 3.7. Insulin
- 3.8. Leptin
- 3.9. TSH
- 3.10. Cortisol
- 3.11. Adrenocorticotrophic Hormone (ACTH)

Completion date

31/10/2010

Eligibility

Key inclusion criteria

1. Patients admitted to any of the five intensive care units (ICUs)
2. Older than 18 years
3. Age, gender and BMI matched healthy subjects

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Age less than 18 years
2. Pre-existing neurological, psychiatric, metabolic, or endocrine disease
3. Intracranial hypertension
4. Intracranial lesions which could influence the hypothalamus-pituitary axis function
5. Gastrectomy
6. Clinically significant liver failure (prothrombin time <30%)
7. Concomitant treatment with thyroid hormones high dose glucocorticoids (>90mg hydrocortisone/day or >18 mg methyl-prednisolone/day), somatostatin, clonidine, dopamine or dopamine antagonist.

Date of first enrolment

01/02/2007

Date of final enrolment

31/10/2010

Locations

Countries of recruitment

Belgium

Study participating centre

Director of the Department of Intensive Care Medicine

Leuven

Belgium

3000

Sponsor information

Organisation

Catholic University Leuven (Katholieke Universiteit Leuven) (Belgium)

ROR

<https://ror.org/05f950310>

Funder(s)

Funder type

University/education

Funder Name

Catholic University Leuven (Katholieke Universiteit Leuven) (Belgium)

Funder Name

Research Foundation, Flanders (Fond Wetenschappelijk Onderzoek Vlaanderen [FWO]) (Belgium)

Funder Name

Supported by long term structural funding Methusalem - funding by the Flemish Government

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	18/04/2013		Yes	No