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The role of ghrelin in acute versus prolonged critical illness

Submission date	Recruitment status	[_] Prospectively registered
20/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2013	Other	

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
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Secondary outcome measures
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)

Overall study start date
01/02/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8 patients and 8 healthy control subjects

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)

Sponsor details
Herestraat 49
Leuven
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3000

Sponsor type
University/education

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

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?
Results article	results	18/04/2013		Yes	No