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Effect of 25-hydroxy vitamin D on inflammation and bone-turnover in critically ill patients

Submission date	Recruitment status	[ ] Prospectively registered
10/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/04/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/04/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ITE vitamin D study (2)

Study information

Scientific Title

Effect of 25-hydroxy vitamin D on inflammation and bone-turnover in critically ill patients: a blinded, prospective, randomised, controlled, parallel group trial

Study objectives
In prolonged critically ill patients, rapid and full normalisation of the vitamin D status (25(OH)D levels) with 25(OH)D supplements will result in less inflammation and improved calcium and bone metabolism, compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Catholic University of Leuven School of Medicine approved on the 25th November 2003 (ref: ML2462)

Study design
Blinded prospective randomised controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Inflammation/calcium and bone metabolism

Interventions
Informed consent will be requested from the next of kin (closest family member or legal guardian) before inclusion in the study. The family member or the patient can withdraw from the trial, at any time, without impact on his treatment or penalty. The investigators confirm that this study concerns a condition that directly threatens patient health and that the adult patient not able to give consent suffers from the condition. The experiment is essential to confirm the results from earlier research in patients who could consent or from other research methods.

Upon ICU admission, patients will be randomly allocated to either:
1. The currently advised vitamin D supplement (a daily intravenous [IV] cholecalciferol supplement of ± 200 IU as part of 10 ml of Cernevit (Clinitec-Baxter, Brussels, Belgium) and a daily IV injection of placebo (ethanol 1 ml)
2. The currently advised vitamin D supplement, an IV loading dose of 200 µg and an IV maintenance dose of 15 µg/day of 25(OH)D, from ICU admission onward and continued for 10 days

25(OH)D will be obtained from Solvay Pharmaceuticals and will be dissolved in ethanol by the hospital pharmacy under laminar flow conditions in glass vials, containing 200 µg/1 ml per vial for the loading dose and 15 µg/1 ml per vial for the maintenance dose. A purity control has been performed on the prepared samples using HPLC (official certificate in addendum). Placebo vials will be prepared by the hospital pharmacy (1 ml ethanol per vial). The vials will be blinded by the hospital pharmacy.

Parenteral nutrition will be given according to routine clinical practice aiming for 25 non-protein calories per kg bodyweight per day and enteral nutrition will be attempted as early as possible.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
25-hydroxy vitamin D

Primary outcome(s)
1. Inflammation and innate immunity patterns, daily during study period (from day 0 till day 10)
2. Bone turnover and vitamin D status: via blood and urine analyses, daily during study period (from day 0 till day 10)

Key secondary outcome(s))
1. Infections, during ICU stay: from admission untill ICU discharge
2. Organ function: Apache (measured upon ICU admission) and Sequential Organ Failure Assessment (SOFA) (measured daily during study period [from day 0 till day 10]) scores
3. ICU stay, measured upon discharge
4. Mortality (ICU, hospital), measured during ICU stay and hospital stay

Completion date
02/09/2004

Eligibility

Key inclusion criteria
1. Patients admitted to any of the four intensive care units with an anticipated Intensive Care Unit (ICU) stay of greater than 10 days
2. Older than 18 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Younger than 18 years
2. Patients suffering from chronic bone disease
3. Patients suffering from parathyroid disease
4. Patients suffering from chronic kidney disease
5. Patients known to be pregnant or nursing
6. Prior treated with glucocorticoids before ICU admission
7. Patients with a 'do not resuscitate' (DNR) code at the time of ICU admission
8. Patients already enrolled in another trial

Date of first enrolment
12/01/2004

Date of final enrolment
02/09/2004

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 (Fonds Wetnschappelijk Onderzoek-Vlaanderen [FWO]) (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration