

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

Submission date
10/04/2009

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
23/04/2009

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
23/04/2009

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ 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)

Primary study design

Interventional

Study design

Blinded prospective randomised controlled parallel group trial

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 (Clintec-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 $\mu\text{g}/\text{day}$ 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 $\mu\text{g}/1$ ml per vial for the loading dose and 15 $\mu\text{g}/1$ 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 until 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 Wetenschappelijk Onderzoek-Vlaanderen [FWO]) (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration