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Special article

COSMOS Project: Haemodialysis scenario in Europe☆

Proyecto COSMOS: escenario de la hemodiálisis en Europa

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The COSMOS project is an observational, prospective, open-cohort, multi-centre European study with 3 years of follow-up, designed, conducted and led by the Bone and Mineral Research Unit at Hospital Universitario Central de Asturias in Spain in collaboration with 227 dialysis centres (21 of them Spanish) in 20 countries in Europe. The main aim of the project is to study Mineral and bone disorders in patients with stage 5D chronic kidney disease. The study was conducted at medium- to large-sized dialysis centres (more than 40 patients/centre) and patients in haemodialysis over 18 years of age who had not previously received a transplant were included.

Dialysis centres in 20 participating countries were randomly selected from the census of European dialysis centres. The total number of patients selected per country was proportional to the number of patients in haemodialysis in that country; therefore, the most populated countries contributed with more patients to the study. Each country was stratified by geographic area and centres were selected randomly within each of these areas so that patients were representative of each country and the entire Europe. For example, Germany was divided into 4 areas (north, south, east and west), Italy and France were divided into 3 areas (north, centre and south), Spain was divided into 3 areas (north, south and east) and Poland was divided into 5 areas (north, south, east, west and centre). At each centre 20 patients were randomly selected.

Following this methodology, 4500 patients were initially randomly selected (baseline cohort). As the study had an open-cohort design, during the 3-year follow-up another 2.297 patients (replacement cohort) were included. These patients replaced those who left the study for whatever reason (death, transplant, transfer to another dialysis unit or any other cause). Therefore, in COSMOS, a total of 6797 patients were studied. This open-cohort design allowed the same number of patients to be maintained throughout the 3-year follow-up and allowed there to be 2 cohorts for study, the baseline cohort and the replacement cohort.

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Table 1 – Site-specific form.

1.Type of Centre
O Hospital based O Non-hospital based
O Academic O Non academic
Funding: O Private O Public
2. Number of chronic haemodialysis patients the day you fill the form: _____
3. How often is a routine bone X-ray profile carried out on patients in dialysis in your centre?
O Every 6 months
O Every year
O Frequency > 1 year
O Not done routinely
O Other
4. What type of X-ray do you perform for the bone x-ray profile?
O Hand O Thoracic
O Skull O Other
O Lumbar
5. When do you routinely measure all the biochemical parameters in your haemodialysis patients?
O Two days after the previous dialysis (mid week)
O Three days after the previous dialysis (post weekend)
6. How often do you measure PTH ?
O Every 1 month O Every_____months
O Every 3 months O Every_____ year
O Every 6 months O Non routinely
7. How often do you routinely measure Ca and P ?
O Every week O Every 4 months O Every 9 months
O Every 2 weeks O Every 5 months O Every 10 months
O Every 1 month O Every 6 months O Every 11 months
O Every 2 months O Every 7 months O Every 12 months
O Every 3 months O Every 8 months
8. Is a standard concentration of calcium used in the dialysate ?
O No O Yes.
If yes: Standard concentration: _____ Units: O mEq/L O mmol/L
9. What PTH assay do you currently use ?
O iPTH (intact) O biPTH (whole PTH)
9b. What PTH assay do you currently use ?
10. With which level of PTH would you consider a patient to require active treatment to suppress PTH levels?
11. In your dialysis patients with secondary hyperparathyroidism that you treat with Vitamin D to suppress PTH, which is your initial preferred route for Vitamin D metabolites administration?
O Oral O Intravenous
and your initial preferred frequency for Vitamin D metabolites administration?
O Daily O Intermittent
12. In a patient that is non-responsive to medical therapy, at what level of PTH do you consider parathyroidectomy ?
13. What type of parathyroidectomy do you carry out?
O Total O Subtotal
O Total with implant O Alcohol/ ethanol injection
14. How many parathyroidectomies were performed in your patients on chronic haemodialysis in the last 12 months ? _____
15. What type of guidelines do you follow?
O K/DOQI
O European algorithm published in NDT
O National guidelines
O None

Source: Taken from Fernandez-Martin et al.[2]

Each centre had to fill in a questionnaire with 15 questions about its routine clinical practice (Table 1, centre-specific questionnaire). In addition, it had to collect patient data including demographic data, comorbidities, treatments and Laboratory parameters (27 questions) (Table 2, patient-specific questionnaire). The same information was collected every 6 months for 3 years (monthly in the case of clinical-chemistry parameters and semi-annually in the case of the others), as well as events having occurred in the previous months (death, hospitalisations, fractures and other matters of interest).

All data were collected by the investigators at each site in a specially designed web form. To minimise errors in data collection, the computer system warned the investigator when the values entered were not within a predetermined range that had been catalogued with reasonable lower and upper limits for that parameter.

The COSMOS study started in February 2005 and data collection ended in July 2010. The complete and detailed design of the study was published during the patient inclusion and data collection period.[1] From July 2010 to December 2011 database structuring, homogenisation and purification were

performed. Given the logistical complexity of the study, each of the 20 participating countries had a national coordinator who was a member of the study's International Committee.

Given the magnitude, multinational nature and complexity of COSMOS, the initial agreements signed between the principal investigator and director of the COSMOS project, and the sponsors and funders of the study (European Renal Association-European Dialysis Transplant Association [ERA-EDTA], Amgen, Fundación Renal Íñigo Álvarez de Toledo [FRIAT], Executive Scientific Committee and International Committee) expressly mentioned the safeguarding and use of the database, which were the responsibility of the manager and principal investigator of the COSMOS project. These agreements specified that the national coordinators could not

Table 2 – Patient-specific form.

1. Year of birth: _____
2. Gender:
   O Male O Female
3. Prescribed Dry weight: _____
4. Height: _____
5. Primary etiology of CKD
6. Date of initiation of any kind of dialysis: _____
7. Type of haemodialysis treatment
8. Haemodialysis hours per week: _____
9. Is the patient diabetic?
   O No O Yes
10. Bone biopsy
    O No O Yes

If yes specify diagnosis of last biopsy

11. Presence of symptomatic, non traumatic, non metastatic fractures in past 12 month
    O No O Yes

If yes specify

   O Vertebral O Radio fractures
   O Hip O Other

12. Parathyroidectomy since start of dialysis
    O No O Yes

If yes specify

   Date of first parathyroidectomy: _____
   If more than one parathroidectomy, specify date of the last parathyroidectomy: _____

13. History of Cardiovascular Disease
    O No O Yes

if yes specify

14. Cigarette smoking status at enrolment date:
   O Active (still smoking) O Former, stopped > 1 year ago
   O Former, stopped <= 1 year ago O Non-smoker
15. Presence of calcification
   O No O Yes

If yes specify technique used to measure calcification:

   O Rx
   O EBCT (Electron Beam Computerized Tomography)
   O MCT (Mutislices Computerized Tomography)
   O Ecography

Location of calcification

   O Valvular O Vascular
   O Soft tissue O Uraemic calcaemic artheriolopathy (calciphylaxis)

16. Calcium concentration in dialysate: _____ Units: O mEq/L O mmol/L
17. PO4 Binders
   O No O Yes O Not available

if yes specify

   O Calcium containing. Total elemental Calcium today: _____ mg/day
   O Magnesium-containing O Poly-anionic gel
   O Aluminium-containing O Other
   O Lanthanum containing

18. Treatment to replete vitamin D physiological levels:
   O 25 (OH) D O None
   O Vit D O Not available
   O Both
19. Treatment with vitamin D metabolites
   O No O Yes O Not available

if yes specify

   O Calcitriol. Dose: _____ micrograms/week
   O Alfacalcidol. Dose: _____ micrograms/week
   O Paricalcitol. Dose: _____micrograms/week

Table 2 – (*Continuación*)

Route:
O Intravenous bolus
O Oral bolus
O Oral daily
20. Calcimimetics
O No O Yes O Not available
if yes specify:
Type of calcimimetics: O Cinacalcet O Other
Frecuency: O Once a day O Twice a day O Once every other day
Maintenance daily dose: _____ mg
21. Erythropoietin-stimulating Agents
O No O Yes
if yes specify:
O Darbepoetin alpha O Generic Rh-EPO alpha
O Rh-EPO alpha O Generic Rh-EPO beta
O Rh-EPO beta O Other. If other specify: _____
Route of administration: O Subcutaneous O Intravenous
Frequency of administration:
O 3 times a week O Once every other week (Q2W)
O 2 times a week O Once every month (QM)
O Once a week (QW) O Once every three weeks (Q3W)
Dose: _____
22. Serum PTH of the previous 6 months
23. Serum P of the previous 6 months
24. Serum Ca of the previous 6 months
25. Serum albumin of the previous 6 months
26. Haemoglobin level of the previous 6 months
27. Serum aluminium of the previous 6 months

Source: Taken from Fernandez-Martin et al.[2]

access raw patient data, safeguarded in Oviedo by the principal investigator of the study, and to have access to data would require the presentation of specific proposal, based on the data collected in the COSMOS database (Tables 1 and 2). The proposal would be submitted to the project director, who would make a decision about its viability and interest after analysing it with the members of the Coordinating Site in Oviedo and with the Executive steering committee.

In the cases in which this proposal is considered to be viable and of interest, the Coordinating Site in Oviedo and the requester would agree upon the protocol of the study and the use of the database, which would always be organised and supervised by the Coordinating Site in Oviedo. Publications obtained from these actions would be prepared jointly by the head of the proposal and by the COSMOS Coordinating Site, who would jointly decide upon the authorship of the publication, following the criteria established in the initial COSMOS publication agreements.

Considering COSMOS to be a strategic project of the Spanish Nephrology Society (SEN) provides an opportunity for SEN members to present proposals following the same conditions established by the Executive steering committee and for the International steering committee mentioned above and to propose studies based on the data collected in COSMOS (see Tables 1 and 2), through a detailed research proposal that will be addressed to the manager and principal investigator of the COSMOS project.

To date, within the COSMOS project, 18 specific studies have been scheduled; 14 were proposed by the Coordinating Site in Oviedo and the other 4 were proposed by the Executive steering committee and the International steering committee. Of these analyses, five have been published,[2–6] two were recently submitted for publication and are under review, seven are in progress with most analysis having been performed and the others are in the preparative stage. Once all scheduled studies are completed and published, in accordance with the agreement signed at the start of the project by the promoters and sponsors of the study, the database will be transferred from the Coordinating Site in Oviedo to the ERA-EDTA Registry.

Conflicts of interest

COSMOS has the sponsorship of the Bone and Mineral Metabolism Department at Hospital Universitario Central de Asturias, the Asturias Society for the Promotion of Bone Research (SAFIM), the European Renal Association-European Dialysis and Transplant Association, the 2008–2011 Spanish National R&D&I Programme and the Instituto de Salud Carlos III (ISCIII), the ISCIII-RETIC REDinREN (RD06/0016/1013 and RD12/0021/1023), the ISCIII (ICI14/00107), the European Regional Development Fund (ERDF), the 2013–2016 Spanish State R&D&I Plan, the 2013–2017 Asturias Science, Technology and Innovation Plan (GRUPIN14-028) and the Fundación Renal Íñigo Álvarez de Toledo (FRIAT). Logistics (meetings, secretary, printing of material, development of website for data collection, etc.) have been funded by Amgen Europe and the Fundación Renal Íñigo Álvarez de Toledo (FRIAT). The authors have no knowledge of any additional relationships or funding that may be perceived as a conflict of interest that may affect the objectivity of this study.

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