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NEFRONA Project: Open-access database

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The NEFRONA project began as an initiative of the research group of the nephrology department of the Arnau de Vilanova University Hospital, Lleida (Spain). It is supported by the Spanish Society of Nephrology (SEN) and sponsored by Abbott Renal Care (www.nefrona.es).

It is an observational, multi-centre study (covering the whole of Spain) conducted in patients with stage 3-5D chronic kidney disease (CKD). The aim of the study is to show how atheromatous disease evolves (4-year trial) and its predictive value with respect to cardiovascular events and mortality. Carotid ultrasound is used to assess atheromatous load and arterial calcification. Demographic and biochemical data are analysed, and serum, plasma, DNA and RNA samples are collected simultaneously.[1]

To check the accuracy of the ultrasound images two itinerant teams visit the different nephrology departments and dialysis centres in order to ensure that the images, which are subsequently sent to Lleida for inspection, are taken by the same technician. Another important aspect of the study is the centralisation of samples in the RedinRen biobank at the University of Alcala.

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The response of Spanish nephrologists has been excellent. At the time of writing this article over 60 nephrology departments and dialysis centres have participated and 1700 patients have been included (Figure 1). For the study to achieve sufficient statistical power we need to reach our target of 2600 patients.

Our aim in this article is to inform readers about one of the objectives of this project: to offer it as a platform which will facilitate and stimulate research amongst Spanish nephrologists.

To facilitate the achievement of this objective the SEN will provide experts who help in the preparation of projects and translation of articles into English to researchers who request it.

To regulate the use of data by researchers and ensure transparency, we provide details of the guidelines approved by the researchers who attended the SEN Conference held in Granada in October.

DATA USE GUIDELINES

We will transfer the entire database to the SEN once the main objectives have been met. This will occur after 4 years, once recruitment has concluded. This will enable long-term

Figure 1. Cities in which collaborating centres are located.

studies, which we are currently unable to envisage, to be conducted.

This transfer of data has already been implemented in other countries in which regulations have been drawn up for ceding data from multi-centre studies to scientific and official organisations (http://www.hcp.med.harvard.edu/ncs/index.php and http://data-donnees.gc.ca/eng/index.html).

We also offer more immediate access. From the end of recruitment (June 2011), data will be available to researchers who propose a project that is approved by the scientific committee.

The data which will be freely available to researchers will consist of: demographic data, ankle-arm index figures, atheromatous load and vascular calcification parameters, ultrasound parameters, biochemical data and "emergent" biomarkers.

With the aim of enriching the diversity of the data which is available we will include:

1. The "emergent" biomarkers analysed with NEFRONA resources.

2. The "emergent" biomarkers analysed with FIS 2011 PI10/00946 ISCIII resources, an observational, prospective, multi-centre study that analyses the mechanisms related to the protective effect of vitamin D on survival and atherosclerosis in chronic kidney disease (PI E. Fernández).

3. The biomarkers which are analysed in the different projects in which the scientific committee authorises the use of biobank aliquots or genetic material.

This model for open use of the database enriched by the biomarkers analysed by different groups has not been previously used. It multiplies research possibilities and stimulates initiatives by researchers who lack possibilities in their own hospitals. For the researchers who use biobank samples, it is a way of repaying Spanish nephrology community for the work its participating researchers have done to achieve the objective set out by NEFRONA, as stored biological samples are a limited and finite common resource.

All this must be subject to the regulatory guidelines presented below:

1. The coordinating group must ensure data accuracy. To do this we have established the following safety measures:

- Images obtained by the same technicians and centralised evaluation.

- An events committee consisting of a nephrologist, a neurologist and a cardiologist, to ensure documented cardiovascular aetiology.

- Specialised personnel will six-monthly update and follow-up the database.

- Sample collection and transfer to the biobank using the measures which are necessary to ensure that samples are viable as far as possible.

2. Scientific committee consisting of: the leading researcher, a member of the research laboratory of the group that coordinates the study, a member of the SEN, a member of the committee of the RedinRen biobank, and an external member who is an expert in the topic in question (to be appointed by the rest of the committee members in each case).

   The criteria for authorising the use of the database will depend on whether biobank sample aliquots are required. Given that the samples are finite, before they are transferred the availability of resources from official agencies or the industry must be accredited to perform the studies which are proposed. Furthermore, the use of sample aliquots must be coordinated with other studies to make the most of samples once they are defrosted.

3. Authorship Guidelines:

- Articles based on the principal objectives will be redacted by the coordinating group and authorship will be defined by this group.

- For articles based on projects presented by other groups, the members of these groups will define the authorship.

- All articles must specify that they are part of the NEFRONA study and linked to IRBLleida, as well as indicate the relevant authors.

- All the articles must include at least one author from the coordinating group, which will be determined in each case.

- If "emergent" biomarkers created in/by other groups are used, a member of the group which developed biomarker/s must be cited, after obtaining prior consent.

  This is why we would like this study to be regarded as a common resource for SEN nephrologists. We also hope that this article, in which unprecedented free exploitation conditions are transparently presented, will stimulate collaborations in order to ensure the statistical power desired for the study.

REFERENCE

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