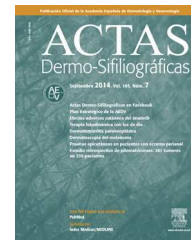




ACTAS Derma-Sifiliográficas

Full English text available at
www.actasdermo.org



OPINION ARTICLE

Research Unit of the Spanish Academy of Dermatology and Venereology Foundation[☆]



La unidad de investigación de la Fundación Academia Española de Dermatología y Venereología

I. García-Doval

Unidad de investigación, Fundación Academia Española de Dermatología y Venereología, Madrid, Spain

Many dermatologists are interested in clinical research. In a survey carried out as part of the project to create a strategic plan for the Spanish Academy of Dermatology and Venereology (AEDV), academy members identified the following as priority challenges: increasing the prestige of dermatology and dermatologists in the eyes of other specialists, health care agencies, and the general public; carrying out high-impact research projects; basing professional practice on scientific evidence; and strengthening training in research. These are also some of the priority objectives of the AEDV.^{1,2}

The Research Unit of the Spanish Academy of Dermatology and Venereology Foundation (FAEDV) was created to meet these needs. The unit commenced operations in February 2012, following a public tender. At that time, the FAEDV already had several ongoing studies for which methodological support had been contracted from external companies. It was therefore considered necessary to create a stable professional structure, specialized in dermatology, which would be a more sustainable solution and would facilitate research within the AEDV.

What are Research Unit's Goals?

The primary objective of the Research Unit is to encourage the participation of AEDV members in methodologically sound multicenter studies, including systematic reviews and clinical practice guidelines. The unit should increase independent scientific output and the national and international profile of AEDV members and working groups, as well as the reputation of the academy itself, while at the same time improving the care of patients with skin diseases. Yet another objective is to increase research collaboration between different centers and to increase the representativeness and quality of the studies undertaken.

In practice, our job is to facilitate the task of setting up and carrying out studies. Our ideal is that, for an individual researcher or an AEDV working group, the simplest way to set up a good research project with the best chance of success should be through the research unit. In this task we have the great advantage that AEDV membership represents over 95% of the dermatologists working in Spain and that the unit is more familiar with the research setting and the dermatological issues than any outside company.

Who Are the People in the Research Unit?

The people currently carrying out the work of the research unit include the administrative and management staff of

[☆] Please cite this article as: García-Doval I. La unidad de investigación de la Fundación Academia Española de Dermatología y Venereología. *Actas Dermosifiliogr.* 2015;106:346–349.

E-mail address: investigacion@aedv.es

the AEDV (who play an essential role in the financial, legal and administrative management of projects), 2 staff members who provide methodological and statistical support, and the external support of project monitors and experts in electronic data collection. The services of documentalists, statisticians, and medical writers are contracted for specific jobs. A key component of the research unit is the group of over 150 academy members throughout Spain who are currently participating or have taken part in studies or courses organized by the unit, and who constitute the basis of its activity.

The unit has a secure online data collection system that complies with all the legal requirements. It also makes use of AEDV's Juan de Azua virtual classroom to train project participants.

The FAEDV's scientific committee supervises the activity of the unit and is responsible for making decisions on its scientific activity in order to ensure that this conforms to the mission and objectives established.

What Does the Research Unit Do?

To illustrate the activity of the research unit, we will describe the studies that it has been involved in since its creation in 2012.

Spanish Registry of Systemic Therapy in Psoriasis (Biobadaderm)

The Biobadaderm study predates the research unit and was one of the factors that influenced the unit's creation because it demonstrated the excellent results that could be obtained using the registry model. The Biobadaderm registry was launched in 2008 and today includes data from over 2000 patients, collected prospectively from 12 hospitals. The unit has been involved in the study since 2012. This project has been a good point of reference for the scientific activity of AEDV. The Spanish Agency for Medicines and Medical Devices (AEMPS) contributes funds to support Biobadaderm in Spain and is represented on the project's scientific committee. Since its creation, the Biobadaderm registry has formed part of the pharmacovigilance strategy of AEMPS. Biobadaderm has also contributed to the international recognition of AEDV's work. The registry is included in the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). Biobadaderm is also one of the most active members of the European Registry for Psoriasis (Psonet), which includes active European, Australian, and Israeli registries. It is represented on Psonet's scientific committee, leads 2 active projects, and has hosted 2 Psonet meetings. Moreover, articles based on Biobadaderm data, in which the research unit has collaborated since 2012, contribute to the dissemination of information about the AEDV's scientific activity.³⁻⁶

Spanish Registry of Mohs Surgery

The Spanish Registry of Mohs Surgery was the unit's first large study and is a collaboration with the AEDV's Dermatologic Surgery, Cutaneous Oncology and Laser Therapy Group

(GECIDOC). The objective is to collect information on Mohs surgery in Spain: its use, the results obtained, the resources used, and the factors influencing outcomes. The study began enrolling patients in June 2013, since when data has been collected from 800 patients treated in 15 hospitals. The first article reporting on this study will shortly be submitted for publication.

Clinical Trial of Photodynamic Therapy in Onychomycosis

Initially, undertaking a clinical trial appeared to be an impossible task for a research unit of our size because of the complexity of the work and organization involved. However, in 2013, following several months of preparation, we started to enroll patients in this randomized clinical trial. In total, 60 patients were enrolled. The trial has been completed and the results will shortly be submitted for publication. This project has opened up the possibility of the FAEDV undertaking other studies, such as clinical trials of nondrug therapies and other independent clinical trials, as well as to the possibility of taking part in international studies, perhaps through the International Federation of Dermatology Clinical Trials Networks.⁷

Prioritization of Therapy Uncertainties in Dystrophic Epidermolysis Bullosa and Prioritization of Therapy Uncertainties in Ichthyosis

The objective of these 2 studies was to produce lists of the priorities for clinical research identified by physicians, caregivers and patients in 2 serious and rare skin diseases: dystrophic epidermolysis bullosa and ichthyosis. In both studies, we have worked together with the Spanish national patient associations (DEBRA and ASIC) as well as, on the international level, the United Kingdom Database of Uncertainties about the Effects of Treatments (UK-DUETS).⁸ Each of these studies involved the participation of over 100 people, including patients, caregivers, and expert clinicians (mostly members of the academy). The resulting article on epidermolysis bullosa has been published on the website of DEBRA International, and its recommendations have been taken into account by DEBRA and have led to changes in that organization's research strategy.^{9,10} The report on the ichthyosis study has not yet been published. As a result of these studies, AEDV has become an affiliate of the James Lind Alliance.¹¹

Systematic Review of Phototherapy in Atopic Dermatitis

A systematic review of phototherapy in atopic dermatitis was undertaken by the participants in one of the courses on the methodology of systematic reviews. The resulting review will be soon published in *Actas Dermo-Sifiliográficas*. Another objective of the research unit is to publish the results of its studies in *Actas* in order to contribute to the journal's development.

Description of the Dermatologic Diseases Diagnosed in Ambulatory Care in Spain

A study is currently being undertaken to collect data on the prevalence of different diseases in outpatient dermatology clinics in Spain and to test the feasibility of implementing a coding system. For the purposes of this study, we will solicit the participation of a representative group of academy members during the coming year. The results will be helpful in planning future studies and in improving the coding of dermatologic diseases in Spain. The study is being carried out in collaboration with the AEDV working group on Epidemiology and Promotion of Health in Dermatology. All of the scientific and legal preparations have already been completed and only the details of funding remain to be confirmed.

The research unit has also collaborated or is beginning to collaborate with other studies, such as the Spanish Surveillance Network on Contact Allergies and the Spanish Lymphoma Registry.^{12,13}

In the area of education, we organize 2 accredited courses each year: an introduction to clinical research in the spring and a course on systematic reviews in the fall. The courses for the coming year (our fourth) are announced on the AEDV website. These courses serve as an introduction to participation in collaborative research and systematic review projects, and the participants gain an understanding of how such projects are undertaken in the research unit. More than 100 members have already attended courses, and it is our hope that this training program will also serve to publicize our scientific activity, as a greenhouse for ideas, and as a means of recruiting participants for new projects.

The research unit can also act as an intermediary in the organization of international studies. In March 2013, for example, the AEDV hosted a meeting of the steering committee of European Dermatoepidemiology Network (EDEN). During the meeting, the members of the network (all leaders in clinical research in their own countries) were informed about the activities of the research unit and the AEDV's collaboration was offered for international studies. Our intention is to maintain this strategy of identifying possible international collaborations and publicizing our own activities.

Is Maintaining the Research Unit a Feasible and Worthwhile Aim?

We believe that the work carried out by the research unit over its two and a half years of operation dispels any doubt about the feasibility and worth of the unit. All of these projects have been useful for the academy and its members. During this period, the unit has been financially self-supporting and has generated sufficient revenues to cover its overhead. One essential aspect of its operation is to reconcile the need for research funding with the need to maintain the scientific rigor and independence that enhance the prestige of our society, always bearing in mind the ultimate goal of improving dermatologic care.

How Can You Participate?

Studies organized by the research unit are open to all AEDV members who fulfill the conditions established by the specific protocol and those laid down by the scientific committee in charge of each project. If you are interested in participating in a study or collaborating in any other way, please contact us at investigacion@aedv.es.

To propose a new study, please contact us. The required steps are described on the AEDV website in the section on research and projects under the title *Unidad de Investigación*. We welcome proposals for multicenter studies that are in line with the interests of the AEDV, and we can provide any help needed in filling out the simple form. Decisions on individual projects are made on the basis of a review of their feasibility and the priorities defined by the scientific committee.

The annual courses on research and systematic review methodology are free, and scheduled dates are posted on the AEDV website calendar.

The Future of the Research Unit?

The research unit is mandated to initiate new studies, including projects undertaken to improve our scientific activity and to enhance the care we provide our patients, including the definition of quality criteria and the evaluation of their use in dermatology practice. Another area of interest is the development of clinical practice guidelines. The future of the research unit will depend on the support of academy members and the participants in studies and courses, and on the work undertaken by the academy's internal bodies.

References

1. Ribera Pibernat M, Moreno Jiménez JC, Valcuende Cavero F, Soto de Delas J, Vázquez Veiga H, Lázaro Ochaíta P, et al. Plan estratégico de la Academia Española de Dermatología y Venereología (AEDV). *FuturAEDV 2013-2017. Actas Dermosifiliogr.* 2014;105:639-54.
2. Moreno-Giménez JC. El plan estratégico de la Academia Española de Dermatología y Venereología. *Actas Dermosifiliogr.* 2014;105:633-4.
3. Medina C, Carretero G, Ferrándiz C, Daudén E, Vanaclocha F, Gómez-García FJ, et al. Safety of classic and biologic systemic therapies for the treatment of psoriasis in elderly: An observational study from national BIOBADADERM registry. *J Eur Acad Dermatol Venereol.* 2014 en prensa.
4. Carretero G, Ferrándiz C, Daudén E, Vanaclocha Sebastian F, Gómez-García FJ, Herrera-Ceballos E, et al. Risk of adverse events in psoriasis patients receiving classic systemic drugs and biologics in a 5-year observational study of clinical practice: 2008-2013 results of the Biobadaderm registry. *J Eur Acad Dermatol Venereol.* 2014 en prensa.
5. Carrascosa JM, Vilavella M, García-Doval I, Carretero G, Vanaclocha F, Daudén E, et al. Body mass index in patients with moderate-to-severe psoriasis in Spain and its impact as an independent risk factor for therapy withdrawal: Results of the Biobadaderm registry. *J Eur Acad Dermatol Venereol.* 2014;28:907-14.
6. Sánchez-Moya AI, García-Doval I, Carretero G, Sanchez-Carazo J, Ferrándiz C, Herrera Ceballos E, et al. Latent tuberculosis

- infection and active tuberculosis in patients with psoriasis: A study on the incidence of tuberculosis and the prevalence of latent tuberculosis disease in patients with moderate-severe psoriasis in Spain BIOBADADERM registry. *J Eur Acad Dermatol Venereol.* 2013;27:1366–74.
7. International Federation of Dermatology Clinical Trials Networks [cited 9 November 2014]. Available at: <http://www.ifdctn.org/>
 8. Database of Uncertainties about the Effects of Treatments (UK DUETs) [cited 9 November 2014]. Available at: <http://www.nice.org.uk/about/what-we-do/evidence-services/database-of-uncertainties-about-the-effects-of-treatments-uk-duets>
 9. Dávila-Seijo P, Hernández Martin A, Morcillo-Makow E, Rajan C, García Doval I. Current dystrophic epidermolysis bullosa research does not match research needs perceived by patients and clinicians. *J Am Acad Dermatol.* 2014;71:1008–11.
 10. Dávila-Seijo P, Hernández-Martin A, Morcillo-Makow E, de Lucas R, Dominguez E, Romero N, et al. Prioritization of therapy uncertainties in dystrophic epidermolysis bullosa: Where should research direct to? An example of priority setting partnership in very rare disorders. *Orphanet J Rare Dis.* 2013;8:61.
 11. The James Lind Alliance [cited 9 November 2014]. Available at: <http://www.lindalliance.org/>
 12. Hernández-Martin A, de Lucas R, Vicente A, Baselga E, Morcillo-Makow E, Arroyo Manzanal MI, et al. Unidades de referencia para epidermolísis ampollosas e ictiosis: una necesidad urgente en España. *Actas Dermosifiliogr.* 2013;104:363–6.
 13. Hernández-Martin A, Aranegui B, Escamez MJ, de Lucas R, Vicente A, Rodríguez-Díaz E, et al. Prevalencia de la epidermolísis ampollosa distrófica en España: estudio poblacional usando el método de captura-recaptura con 3 fuentes de datos. Evidencia de la necesidad de mejora en la atención sociosanitaria. *Actas Dermosifiliogr.* 2013;104:890–6.