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FACULTEIT GENEESKUNDE EN FARMACIE

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UITNODIGING

Voor de openbare verdediging van het
doctoraatsproefschrift van

Joan-Carles ARCE

woensdag 3 juni 2009

U wordt vriendelijk uitgenodigd op de openbare verdediging van het proefschrift van

Joan-Carles ARCE

'Methodological and clinical issues to be considered in the design of efficacy trials in assisted reproductive technologies'

Op **woensdag 3 juni 2009** om **17 uur** in auditorium **P. Brouwer** van de Faculteit Geneeskunde & Farmacie, Laarbeeklaan 103, 1090 Brussel

Situering van het proefschrift

Scientific evidence derived from optimal trial designs should guide decisions on treatment strategies. Continuing efforts are needed to identify methodological pitfalls in the design of efficacy trials in ART. Areas for improvements include well-defined study populations, stricter protocols, harmonisation of the type and doses of concomitant fertility medications, reduction of variability arising from different centre protocols for stimulation goals, dose adjustments, timing of triggering final follicular maturation and luteal phase support, as well as different procedures and policies for embryo transfer and freezing.

The thesis provides a theoretical rationale for considering more rigid designs for efficacy trials in ART and has documented that it is feasible to conduct a study applying these theoretical methodological considerations into clinical research practice. A specific trial was used to illustrate the link between design decisions and practical execution, and can be viewed as a step forward in improving the design of efficacy trials in ART and as a methodological reference point for future trials. The approach used in this case study comparing gonadotrophin preparations could be extrapolated to many other areas of interest in ART, and the concepts are applicable to RCTs in general, covering both academia-initiated clinical trials as well as larger scale industry-based clinical research.

Curriculum Vitae

Joan-Carles Arce graduated from medical school from the Autonomous University of Barcelona in 1987, and completed in 1992 his postdoctoral fellowship in Reproductive Physiology during his training at the division of Reproductive Endocrinology and Infertility at the University of Connecticut Health Center in Farmington, USA. After spending several years conducting clinical trials within various aspects of women's health care in both academia and the pharmaceutical industry, Dr Arce became director of clinical development of the fertility area for Novo Nordisk. Dr Arce joined Ferring Pharmaceuticals in Denmark in 2002, and he currently holds a position as Vice President, Clinical Research & Development, where he is responsible for the design, planning and execution of all drug development activities in the OB&GYN therapeutic area as well as for the company unit implementing systems, processes and training activities related to clinical development overall.

Among the main interests of Dr Arce are to develop trial designs representing the optimal balance between what is ideal from a scientific and clinical point of view and what is feasible from an operational and practical perspective.