Asignatura: Methodology of Clinical Trials
Código: 31668
Centro: Facultad de Medicina. U.A.M.
Titulación: Máster en Investigación Farmacológica
Nivel: Máster
Tipo: Obligatoria
Nº de créditos: 2 ECTS
Curso académico: 2017-2018

1. COURSE TITLE

Methodology of Clinical Trials

1.1. Course number

31668

1.2. Content area

General Module

1.3. Course type

Compulsory

1.4. Course level

Master

1.5. Year

1st

1.6. Semester

First Semester

1.7. Language

English

1.8. Prerequisites

Higher degree (Bachelor's Degree) in Medicine, Pharmacy, Biology, Biochemistry, Chemistry, Veterinary Science, Psychology, Nursing or other related degree in the area of Health Sciences.

1.9. Minimum attendance requirement

90%

1.10. Faculty data

Lecturer(s)- Coordinator: ANTONIO JAVIER CARCAS SANSUÁN
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Contact hours: Previous e-mail appointment is required

1.11. Course objectives

Abilities:

Basic and general

- To obtain the knowledge and understanding enabling an adequate and original approach in developing and/or applying ideas in the context of clinical research.
- To acquire communication skills enabling transmission of scientific knowledge and its rationale in a clear and unambiguous way to both specialist and non-specialists.
- Students should possess the learning skills allow them a self-directed and autonomous and long-lasting learning.
- Acquire the knowledge and skills needed to pursue an innovative and quality research in Clinical Pharmacology.

Transversal:

- Ability to conduct a self-study plan, perform autonomous scientific literature search at technical and regulatory levels.
- Ability to communicate scientific knowledge in both specialized and general environments, including teaching.

Specific:

- To ascertain the therapeutic potential of new biological, gene and cell therapies and the methodological basis of their clinical evaluation.
- Learn the basics about the development of new drugs and the scientific, ethical and regulatory aspects that condition it.
- Be able to carry out the basic data management and analysis in clinical trials as well as to properly interpret their results.

1.12. Course contents

1. Theoretical program

1. Introduction to clinical research with drugs (2 hours):
1.1. Clinical research with drugs: types of studies
1.2. The phases of clinical research with drugs
2. The methodological basis of clinical trials (8 hours).
2.1. Clinical trials: definitions, methodological basis, the development of a clinical trial.
2.2. Objectives definition, selection of endpoints. Defining the study population.
2.3. Types of design: parallel, crossover, sequential, therapeutic equivalence.
2.4. Bias in clinical trials. Randomisation and blinding.
2.5. Evaluation and detection of ADRs in clinical trials.
2.6. Analysis and interpretation of the results of a clinical trial.
2.7. Methods of synthesis of scientific evidence: the meta-analysis.
2.8. Pharmacoeconomic analysis. Principles of pharmacoeconomic analysis in the clinical trials.
3. Clinical development and regulatory ethical espects (2 hours).
3.1. The regulation of clinical drug development. National and international clinical trials.
3.2. The ethics of clinical research: the role of investigators, regulators and ethics committees. The patient informed consent.

2. Practical program (8 hours)

- Example of sample size predetermination. Importance of sample size in the interpretation of negative results. (1 hours)
- Intention to treat analysis. Assessment and analysis of exclusions in CTs. Generalization of the results. Examples of the literature. (1 hour)
- Evaluation variables in clinical trials, its importance in drug development. Surrogate and composite variables: advantages and disadvantages. Analisis of subgroups. (2 hours)
- Publication bias and communication. Clinical Trials Registries. (1 hour).
- Evaluation of published clinical trials: a practical example and use of evaluation forms (1 hour).
- Conflict of interests in the implementation and communication of results of clinical trials (1 hour).
- Practical examples: Communication of adverse drug reactions in the context of a clinical trial and post marketing surveillance. (1 hour).

1.13. Course bibliography

- Pocock et al. Making Sense of Statistics inClinical Trial Reports. Part 1 of a 4-Part Series on Statistics for Clinical Trials. JACC V O L . 6 6 , N O . 2 2 , 2 0 1 5 (h t t p : / / d x . d o i . o r g / 1 0 . 1 0 1 6 / j . j a c c . 20 1 5 . 1 0 . 0 1 4).
- Pocock et al. Statistical Controversies in Reporting of Clinical Trials. Part 2 of a 4-Part Series on Statistics for Clinical Trials. JACC V O L . 6 6 , N O . 2 3 , 2 0 1 5 (h t t p : / / d x . d o i . o r g / 1 0 . 1 0 1 6 / j . j a c c . 20 1 5 . 1 0 . 0 2 3)
- Pocock et al. Design of Major Randomized Trials. Part 3 of a 4-Part Series on Statistics for Clinical Trials. JACC V O L . 6 6 , N O . 2 4 , 2 0 1 5 (h t t p : / / d x . d o i . o r g / 1 0 . 1 0 1 6 / j . j a c c . 2 0 1 5 . 1 0 . 0 3 6).
- Pocock et al. Challenging Issues in Clinical Trial Design. Part 4 of a 4-Part Series on Statistics for Clinical Trials. JACC V O L . 6 6 , N O . 2 5 , 2 0 1 5 (h t t p : / / d x . d o i . o r g / 1 0. 1 0 1 6 / j . j a c c . 2 0 1 5 . 1 0 . 0 5 1)
- Jadad AR and Enkin MW. Randomized Controlled Trials. Questions, Answers, and Musings. Second edition. BMJ Books. Blackwell Publishing. 2007. ISBN: 9781405132664.
- Lubomirov Hristov R, Ruiz Algueró M, Carcas Sansuán A. Ensayo clínico: Tipos de diseño. En: Manual del Residente de Farmacología Clínica. Editado por la Sociedad Española de Farmacología Clínica. 2002; pp: 89-113.
- Carcas AJ. Investigación comparativa de la efectividad. En: Dal-Re et al. Luces y sombras en la investigación clínica. Madrid: Triacastela; Fundació Víctor Grífols I Lucas, 2013. 592 págs. ISBN: 978-84-95840-83-7.
- Egger, M., Davey Smith, G., & Phillips, A. N. (1997). Meta-analysis: Principles and Procedures. British Medical Journal, 315(7121), 1533-1537.
- Crombie IK and Davies HT. What is meta-analysis?. http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/meta-an.pdf.
- Etminan et al. Pharmacoepidemiology I: A Review of Pharmacoepidemiologic Study Designs. Pharmacotherapy 2004; 24(8): 964-969.
- Etminan, M. Pharmacoepidemiology II: The Nested Case-Control Study—A Novel Approach in Pharmacoepidemiologic Research. Pharmacotherapy 2004; 24: 1105–1109. doi: 10.1592/phco.24.13.1105.38083.
- Soto J. Estudios de farmacoeconomía: ¿por qué, cómo, cuándo y para qué?.

http://scielo.isciii.es/pdf/medif/v11n3/hablemosde.pdf?origin=publication_detail.

2. Teaching methodology

1. **Lectures.**
2. **Seminars**: led by the teacher adressing practical aspects in the design or interpretation of clinical trials as sample size predetermination or communication of adverse reactions.
3. **Seminars presented by the students** after individual work and tutorized by the teacher. In this case students made a presentation based on one or more articles published that allows discussion of relevant aspects of clinical trial methodology (i.e., the importance of intention to treat analysis, publication and communication bias) or ethical issues in conducting clinical trials.

3. Student workload

		Nº de horas	Porcentaje
Presencial	Theoretical lectures	12 h	50%= 25 h
	Practical classes	--	
	Tutorial time along the semester	4 h	
	Seminars	8 h	
	Other	--- h	
	Final Exam	1 h	
No presencial	Practical activities and preparation of work in group/seminars	8 h	50%= 25 h
	Weekly study time	12 h	
	Exam preparation	5 h	
Total: 25 hours x 2 ECTS		**50**	

4. Evaluation procedures and weight of components in the final grade

Exam _____ 70%
Composed by multiple choice questions and questions of thrue/false response).

Seminars, personal work_____ 30%
The student receives one or more articles that he/she must analyze and present to the other students for discussion.
Attendace and participation_____ 10%

It is planned to carry out an extraordinary examination or/and extraordinary essay if needed. The faculty will decide the format of the examination/essay by considering the aspects in which the student failed.

5. Course calendar

Week	Contents	Contact hours	Independent study time
1	1.Introduction to clinical investigation with drugs 2. Clinical Trials: the basics on methods. 3. Clinical development of drugs: ethical and regulatory aspects	2 hours 8 hours 2 hours	2 hours 8 hours 2 hours
2	4. Practical program Tutorials	8 hours 4 hours	8 hours
3	Exam	1 hours	5 hours