UNIVERSIDAD AUTÓNOMA DE MADRID

33201 - METHODOLOGY IN CLINICAL TRIALS

This is a non-sworn translation intended to provide students with information about the course

Information of the subject

Code - Course title: 33201 - METHODOLOGY IN CLINICAL TRIALS

Degree: 721 - Máster en Investigación Farmacológica (2018)

Faculty: 106 - Facultad de Medicina

Academic year: 2023/24

1. Course details

1.1. Content area

In this subject the bases to develop clinical trials in humans is addressed. In addition, the tools for a critical and systematic evaluation of a protocol or a published clinical trial are presented and the functioning of the clinical research ethics committees (CREC). Likewise, regulatory and ethical issues of conducting clinical trials with drugs will be also presented.

1.2. Course nature

Compulsory

1.3. Course level

Máster (EQF/MECU 7)

1.4. Year of study

1

1.5. Semester

First semester

1.6. ECTS Credit allotment

2.0

1.7. Language of instruction

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. B2 o similar level of English language.

1.9. Recommendations

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1.10. Minimum attendance requirement

Minimum attendance 80% (theoretical and seminars/resolution of problems)

1.11. Subject coordinator

Antonio Javier Carcas Sansuan

https://autoservicio.uam.es/paginas-blancas/

1.12. Competences and learning outcomes

1.12.1. Competences

BASIC AND GENERAL
GE1 - Acquire the knowledge, skills and abilities necessary to carry out an innovative quality research in Pharmacology

CB6 - Possess and understand knowledge that provides a basis or opportunity to be original in the development and / or application of ideas, often in a research context

CB9 - That the students know how to communicate their conclusions and their knowledge to specialized and non-specialized publics in a clear and unambiguous way

CB10 - That students possess the learning skills that allow them to continue studying in a way that will be largely self-directed or autonomous.

TRANSVERSAL
T2 - Ability to carry out effective scientific and technical communication, both in a specialized environment and in more general environments, including the educational.

T1 - Ability to carry out a self-learning plan, perform an autonomous consultation of the bibliography and databases at the scientific, technical or regulatory level.

SPECIFIC
ES-2 - Know the potential of new biological, genetic and cellular therapies

ES-3 - Know the basic aspects about the design and obtaining new drugs, both at a chemical and biotechnological level, as well as the scientific, ethical and regulatory aspects that condition it.

ES-8 - Be able to carry out the handling and analysis of data from pharmacological investigations

1.12.2. Learning outcomes

The students will become familiar with the methodology of the clinical trial, as the main methodology of study in humans, as well as with the ethical and deontological concepts associated with this methodology.

1.12.3. Course objectives

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1.13. Course contents

1. Theoretical program
Introduction to clinical research with drugs (2 hours):

Drug development of drugs: from preclinical to human studies (1 hr).
Clinical drug development: phases and type of studies (1 hr)
The methodological basis of clinical trials (8 hours).
Clinical trials: definitions, methodological basis, the development of a clinical trial (1 hr)
Objectives definition, selection of endpoints. Defining the study population (1 hr)
Types of design: parallel, crossover, sequential, therapeutic equivalence (1 hr)
Bias in clinical trials. Randomisation and blinding (1 hr)
Safety evaluation in clinical trials (1 hr)
Analysis and interpretation of the results of a clinical trial (1 hr)
Methods of synthesis of scientific evidence: the meta-analysis (1 hr)
Pharmacoeconomic analysis. Principles of pharmacoeconomic analysis in the clinical trials (1 hr)
3. Clinical development and regulatory ethical espects (2 hours).
The regulation of clinical drug development. National and international clinical trials (1 hr)
The ethics of clinical research: the role of investigators, regulators and ethics committees. The patient informed consent (1 hr)
2. Practical program (8 hours)
2.1. Internal validity. Assessment of bias. Examples (1 hr)
2.2 End-points in clinical trials and its clinical relevance (composite, surrogate) (1 hr)
2.3. External validity and generalization of results (1 hr)
2.4. Interpretation of positive results. Examples (2 hr)
2.5 Interpretation of negative results. Examples (2 hr)
2.7. Publication bias and communication. Conflict of interests in the implementation and communication of results of clinical trials (1 hr)

1.14. 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-and-learning methodologies and student workload

2.1. Contact hours

TOTAL HOURS OF METHODOLOGY IN CLINICAL TRIALS			
		Nº of hours	%
Presencial	Lectures	12	50
	Tutorial time along the semester	4	
	Seminars	8	
	Final Exam	1	
No presencial	Practical activities and preparation of work in group/seminars	8	50
	Weekly study time	12	
	Exam preparation	5	
Total: 25 hours x 2 ECTS		**50**	

2.2. List of training activities

LECTURES will provide organized and structured information elaborated by the Lecturer. The lecture content will include the knowledge already established or in very advanced situation, obtained from textbooks, bibliographic reviews, and relevant original papers. Lectures will take 50 minutes, using audiovisual presentations that can be available in the teaching web page.

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.

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. Evaluation procedures and weight of components in the final grade

3.1. Regular assessment

The final mark (for both ordinary and extraordinary evaluations) will be the result of the marks obtained in the final exam (70%) and in the continuous evaluations (30%).

IMPORTANT: To pass the subject it is compulsory to attend 80 % of the scheduled activities and to have a minimum score of 5/10 points in the final exam. If the student does not pass the

exam in the ordinary call, he/she will need to attend the extraordinary exam.

3.1.1. List of evaluation activities

Final exam characteristics (70%)

The exam (for both the ordinary and the extraordinary call) will be mainly based on multiple choice questions and it can also include short questions. The type and date of exam will be announced previously by the coordinator.

Continuous evaluation (30%). Includes:

- Attendance to classes and seminars (10%)
- Seminars (20%). These exercises will be performed during the classroom or non-face-to-face through the Moodle platform. These exercises may have different format depending on the lecturer. They may include: short questions, multiple choice or true/false questions, problems or simulations. The lecturer will announce previously the type and the date of each exercise.

3.2. Resit

It is planned to carry out an extraordinary examination or/and extraordinary essay if needed.

3.2.1. List of evaluation activities

The faculty will decide the format of the examination/essay by considering the aspects in which the student failed.

4. Proposed workplan

Schedule will be uploaded in Moodle:https://moodle.uam.es/