Discipline MCP5863
Planning, Implementation and Development of Randomized Clinical Trials

Concentration area: 5131

Creation: 13/06/2024

Activation: 13/06/2024

Credits: 2

Workload:

Theory (weekly)	Practice (weekly)	Study (weekly)	Duration	Total
14	9	7	1 weeks	30 hours

Professors:

José Carlos Nicolau

Otavio Berwanger

Objectives:

Develop the capacity to raise adequate hypotheses for the proposition of unicentric and multicentric randomized clinical trials in cardiovascular diseases. Discuss fundamental concepts of planning and coordination of randomized clinical trials in cardiovascular diseases. Training of students in conducting randomized clinical trials based on national and international good clinical practice rules.

Rationale:

Cardiovascular diseases are the main cause of morbidity and mortality worldwide, as in Brazil (1), so that the search for safe and effective therapeutic interventions for these conditions is a major priority in terms of Public and Private Health. The gold standard method of research for evaluating the efficacy and safety of interventions aimed at the treatment and prevention of cardiovascular diseases is the randomized clinical trial (2-6), so that the adequate knowledge of this research methodology is mandatory for professionals interested in performing clinical research on cardiovascular diseases (7). It is important to emphasize that, contrary to the understanding of some, the correct definition of a randomized clinical study includes all research in humans that intends to randomly analyze any intervention (drug or non-drug), thus varying from a few dozen individuals to several hundreds (8)

Content:

How to justify the need for a Randomized Clinical Trial. How to define inclusion and exclusion criteria. Primary and secondary objectives. Surrogate endpoints. Industry opinion, the scientific societies and regulatory agencies. The "good question" and the answer to it. Outcomes (primary and How to set up data collection cards (CRF- "case report forms"); how to implement a database; methods for data quality control. Structuring and managing a research center: basic concepts of structuring, planning, financial and contractual controls. Ethical Aspects and Good Clinical Practice in research, with emphasis on conducting randomized studies. Main aspects in bias prevention (selection methods of participating subjects, randomization techniques, blinding, intention-to-treat analysis, prevention of follow-up losses, early study interruption by benefit). Similarities and differences between the large international multicenter study and the doctoral thesis.

Type of Assessment:

Attendance, demonstrated interest in classes and performance in seminars.

Notes/Remarks:

Minimum number of students: 06 Maximum number of students: 30

Bibliography:

World Health Organization. The World Health Report 2018 – Global Health Observatory data. htttp://www.who.int/gho/mortality_burden_disease/en/. Accessed on March 20, 2019. Sackett DL. The Tactics of Performing Therapeutic Trials. In: Clinical Epidemiology (Haynes et al. 2006) Second Edition. DeMets DL, Califf RM. A historical perspective on clinical trials innovation and leadership: where have the academics gone? JAMA. 2011;305(7):713-4 Schulz KF, Grimes DA. Blinding in randomised trials: hiding who got what. Lancet. 2002;359:696-700. Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. Lancet. 2002; 359:614-8. Lader EW, Cannon CP, Ohman EM, Newby LK, Sulmasy DP, Barst RJ, Fair JM, Flather M, Freedman JE, Frye RL, Hand MM, Jesse RL, Van de Werf F, Costa F; American College of Cardiology Foundation. The clinician as investigator: participating in clinical trials in the practice setting. Circulation. 2004;109(21):2672-9 Collins et al. Reliable assessment of the effects of treatment on mortality and major morbidity, I: clinical trials. Lancet 2001; 357: 373–80 Yusuf S, Bosch J. Independent design and conduct of clinical trials. ClinTrials. 2006;3(6):503-7.

Class type:

Presencial