האוניברסיטה העברית בירושלים
THE HEBREW UNIVERSITY OF JERUSALEM

The Hebrew University of Jerusalem

Syllabus

CLINICAL TRIALS - 98481

Last update 14-09-2014

HU Credits: 2

Degree/Cycle: 2nd degree (Master)

Responsible Department: Braun School of Public Health

Academic year: 2015

Semester: 2nd Semester

Teaching Languages: Hebrew

Campus: Ein Karem

Course/Module Coordinator: Prof. Ora Paltiel

Coordinator Email: orap@hadassah.org.il

Coordinator Office Hours: No specific office hours. Contact Prof. Paltiel by mail

Teaching Staff:

Ora Paltiel
Prof Orly Manor
Prof Yechiel Friedlander

Course/Module description:

Clinical trials are the basis on which therapeutic decisions are made. New therapies and intervention must, nowadays, undergo rigorous experimental evaluation before they are approved. The field of Clinical trials includes study design, organization, monitoring, statistical analysis and ethical issues. Because of the problematics of conducting clinical trials with a large enough sample size to give definitive results, meta-analysis, combining results of several trials has been devised.

Course/Module aims:

This course aims to provide the student with theoretical, methodological, and statistical tools with which to evaluate and design clinical trials. Practical issues of data monitoring, new drug approval as well as ethical issues will be addressed. Finally an approach to meta-analysis will be provided. The students will have an opportunity to design a protocol in their field of interest.

Learning outcomes - On successful completion of this module, students should be able to:

1. Compose inclusion and exclusion criteria
2. Calculate sample size and power for continuous and categorial outcomes
3. Build a randomization platform
4. Recognize different clinical trials designs, their strengths and weaknesses
5. Be able to perform and analyze a meta-analysis
6. Write a clinical trials protocol
7. Be familiar with ethical guidelines for clinical trials

Attendance requirements(%):

Teaching arrangement and method of instruction: Lectures, Exercises, protocol preparation

Course/Module Content:

Introduction to clinical trials

Study population
Randomization
Sample size
Special designs
Analysis 1 Basic
Analysis 2 Multiplicity
control of bias
Ethics including GCP
Protocols, data monitoring, recruitment
Meta-analysis

Required Reading:

Additional Reading Material:

Course/Module evaluation:
End of year written/oral examination 0 %
Presentation 0 %
Participation in Tutorials 0 %
Project work 50 %
Assignments 50 %
Reports 0 %
Research project 0 %
Quizzes 0 %
Other 0 %

Additional information:
Prerequisites
Statistics (the 7 credit course). Students are encouraged to take/have taken more advanced statistics courses. Obligatory course for Master's in Clinical Epidemiology.