האוניברסיטה העברית בירושלים
THE HEBREW UNIVERSITY OF JERUSALEM

The Hebrew University of Jerusalem

Syllabus

CLINICAL TRIALS - 98481

Last update 29-01-2024

HU Credits: *2*

Degree/Cycle: *2nd degree (Master)*

Responsible Department: *Public Health*

Academic year: *0*

Semester: *2nd Semester*

Teaching Languages: *Hebrew*

Campus: *Ein Karem*

Course/Module Coordinator: *Prof. Ora Paltiel*

Coordinator Email: *orap@hadassah.org.il*

Coordinator Office Hours: *Contact Prof. Paltiel by mail*

Teaching Staff:

Prof Ora Paltiel,
Dr. Wiessam Abuahmad,
Ms. Chaya Mazuz

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. Be familiar with ethical guidelines for clinical trials

Attendance requirements(%):

Attendance required for GCP certification

Teaching arrangement and method of instruction: Lectures, Exercises, quiz

Course/Module Content:

Introduction to clinical trials
Study population
Randomization

Sample size
Special designs
Analysis 1 Basic
Analysis 2 Multiplicity
control of bias
Ethics i
Protocols, data monitoring, recruitment

Required Reading:
Up to 10 articles are used to illustrate the learning material.
For exercises, and additional 6 articles are used.

Additional Reading Material:

Grading Scheme:
Submission assignments during the semester: Exercises / Essays / Audits / Reports / Forum / Simulation / others 80 %
Mid-terms exams 20 %

Additional information:
Prerequisites
Statistics
Students are encouraged to take/have taken more advanced statistics courses as well as epidemiology and research methods. Obligatory course for Master's in Clinical Epidemiology and Pharm D.