



METODOLOGIA CLINICA APPLICATA AGLI STUDI DI RICERCA

8 CFU - 1° Semester

Teaching Staff

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LEARNING OBJECTIVES

▪ **Pharmacology: safety in therapy management**

Students will acquire knowledge about basic principles in Pharmacology, such as pharmacokinetics and pharmacodynamics, drugs mechanisms, signal transduction pathways, adverse drug reactions. Furthermore, an overview of major drug classes mainly used in hospital will be presented, to promote the correct use of drugs and to avoid eventual life-threatening adverse reactions or drug interactions.

▪ **CLINICAL METHODOLOGY APPLIED TO RESEARCH STUDIES**

Provide learners with knowledge to understand the implementation, interpretation and application of clinical trials in diseases of Internal Medicine. Analyze the various types of clinical studies. The

following topics will be studied in detail: evidence-based medicine (Evidence-Based Medicine, EBM), levels of evidence, degree of recommendations, consensus conferences, guidelines, recommendations based on studies available in Internal Medicine and diagnostic-therapeutic protocols in Internal Medicine. Clinical trials will be illustrated and analyzed in the management of the most frequent internal diseases (cardiocirculatory, metabolic, gastroenterological, pulmonary, neoplastic).

▪ **General pathology applied to trials**

Describe how human cells function organized in tissues and organs; - Describe organs functions of the human body, their dynamic integration into apparatuses and the general mechanisms of functional control in physiological use conditions; - Indicate the main functional findings in healthy humans; - List and describe the main causes of disease in humans; - Describe the main pathogenetic and pathophysiological mechanisms at the cell, tissue, organ and system level; - Describe the defense mechanisms of the organism; - Describe the main pathogenic organisms and their mechanisms of action.

COURSE STRUCTURE

▪ **Pharmacology: safety in therapy management**

Lectures. Students are invited to actively participate with questions, comments and thoughts related to covered topics.

In case lectures will be held in a mixed condition (both in front of students and online) or online only, required changes will be adopted even if not clearly stated in this section, in order to comply the planned program as reported in the Syllabus

▪ **CLINICAL METHODOLOGY APPLIED TO RESEARCH STUDIES**

The lectures will be held in frontal mode with the help of slides in power-point format, illustration and commentary on the images of instrumental investigations, report on clinical cases.

If the teaching is given in a mixed or remote mode, the necessary changes may be introduced with respect to what was previously stated, in order to respect the program envisaged and reported in the syllabus.

▪ **General pathology applied to trials**

Frontal lessons.

Should teaching be carried out in mixed mode or remotely, it may be necessary to introduce changes with respect to previous statements, in line with the programme planned and outlined in the syllabus.

DETAILED COURSE CONTENT

▪ **Pharmacology: safety in therapy management**

- Principles of Pharmacology

- Development of new drugs
- Pharmacokinetics and pharmacodynamics
- Variability factors that influence the pharmacological response
- Risks and precautions for correct drug therapy
- Adverse drug reactions
- Neurotransmitters (synthesis, release, receptors)
- Drugs active on the systems: cholinergic, catecholaminergic, GABAergic, histaminergic, serotonergic
- Drugs of the gastrointestinal system (antiemetics, IPP, antacids, cytoprotectors)
- Drugs of the cardiovascular system (CBB, inhibitors of the renin-angiotensin system, diuretics, haemostasis drugs)
- Drugs of the arachidonic acid cascade (glucocorticoids and NSAIDs)
- Drugs used in diabetes mellitus
- Antimicrobial and antineoplastic drugs (penicillins, cephalosporins, macrolides, aminoglycosides, quinolones, antimetabolites, mitotic spindle inhibitors, alkylating agents and platinum compounds, molecular target drugs)

▪ **CLINICAL METHODOLOGY APPLIED TO RESEARCH STUDIES**

Knowledge of the main pathologies of international interest of the gastrointestinal system, of the liver, of the cardio-circulatory system, of the respiratory system, of the kidney, of lipid metabolism and of glucose metabolism. Knowledge of biostatistics elements.

The educational objectives of the teaching of Gastroenterology are the knowledge of epidemiology, etiopathogenesis, symptoms, diagnosis, elements of therapy and complications of the main diseases of the digestive system.

The Gastroenterology Course will provide the learner with an updated summary on the main diseases of the gastrointestinal tract, liver, biliary tract and pancreas in relation to: epidemiology, etiopathogenesis, symptoms, diagnosis and elements of drug therapy. The course also aims to start a process of critical maturation of knowledge of the diagnostic options applicable to pathologies of gastroenterological relevance. Knowledge will also be supported by the vision of explanatory iconographic material, slides of: X-ray images, CT, MRI, Endoscopy of the digestive system. Diagnostic algorithms, and national and international guidelines will be discussed.

The lectures will be held in frontal mode with the help of slides in Power-Point format, illustration and commentary on the images of instrumental investigations, report on clinical cases.

If the teaching is given in a mixed or remote mode, the necessary changes may be introduced with respect to what was previously stated, in order to respect the program envisaged and reported in the syllabus.

- Clinical Studies (definition and purpose)
 - Types of Clinical Studies: epidemiological, observational, interventional, case control (safety and efficacy studies of new drugs or new devices), pre-clinical safety studies.
 - Role of the Ethics Committee in the development of clinical trials.
 - Interpretation and evaluation of evidence of efficacy.
 - Evidence-Based Medicine (EBM)
 - Levels of evidence.
 - Degree of recommendations.
 - Consensus conference.
 - The guidelines: recommendations based on the studies available in Internal Medicine.
 - Diagnostic-therapeutic protocols in Internal Medicine.
 - Clinical trials in the management of Acute Pulmonary Embolism.
 - Clinical trials in the management of hepatic steatosis (NAFLD), non-alcoholic steatohepatitis (NASH) and alcoholic steatohepatitis.
 - Clinical trials in the management of chronic hepatitis and HCV-related cirrhosis.
 - Clinical trials in the management of HCV extrahepatic manifestations.
 - Clinical trials in the management of cardiovascular risk from HCV.
 - Clinical trials of the efficacy and safety of antiviral therapies for chronic HCV infection.
 - Clinical trials in defining the criteria for access to therapies with 2nd generation Direct Antiviral Agents (DAAs) in the treatment of chronic HCV infection.
 - Clinical trials in the management of cardiovascular risk in dyslipidemias, in diabetes mellitus, in the obese / overweight subject, in arterial hypertension.
- **General pathology applied to trials**
 - Introduction to General pathology
 - Concept of homeostasis and disease
 - Causes of physical diseases
 - Causes of chemical diseases
 - Causes of biological diseases
 - Cellular pathology
 - Cell damage and adaptive response
 - Innate and specific immunity
 - Phagocytosis and the complement system
 - Immunopathogenic reactions
 - Acute and chronic inflammation
 - Clinical and Preclinical Studies "Clinical Trials"
 - Practice on studying clinical trial articles

TEXTBOOK INFORMATION

- **Pharmacology: safety in therapy management**
 1. ROSSI F., CUOMO V., RICCARDI C., Farmacologia per le professioni sanitarie, Ed. Minerva Medica
 2. Hitner, Nagle, Principi di Farmacologia, Zanichelli
 3. Clark, Finkel, Rey, Le basi della Farmacologia, Zanichelli (for General Pharmacology only)
- **CLINICAL METHODOLOGY APPLIED TO RESEARCH STUDIES**

- **Medicina Interna** Autore: Massini Renato; Izzi Donatello; Marchetti Patrizia; Passeretti Francesca; Recine Umberto, Editore: McGraw-Hill Italia
- **Medicina Interna per Scienze Infermieristiche** Autore: Antonelli Incalzi Raffaele, Editore: PICCIN EDITORE
- **HARRISON** - Principi di Medicina Interna - Il manuale- McGraw-Hill

- **General pathology applied to trials**

Slides lesson

Pontieri: Patologia Generale

Robbins: Patologia Generale

Rubin: Patologia generale
