Pharmacological Research in Humans

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DESCRIPTION

The main objective (CIM) is to perform clinical drug trials and/or clinical research ensuring compliance with the legal, ethical and methodological requirements stated in international standards.

Clinical trials (phase I): Activity is focused on the evaluation of systemic and local tolerability, pharmacokinetics, bioavailability and bioequivalence (generics) as well as pharmacological effects.

Studies are also performed in healthy volunteers and special populations with specific characteristics, such as the healthy elderly, obesity, postmenopausal women, or those renal or hepatic insufficiency.

Clinical trials (phases Ib, IIa): Specific interventions are performed in this phase, and controlled monitoring of the patient's response is required.

Furthermore, support from the integration of administrative, computer, and statistical systems enables the optimal performance of clinical studies.

MAIN LINES OF RESEARCH

- Phase I clinical trials (healthy volunteers) whose main objectives include: first-time-in-humans, safety and tolerability, pharmacokinetics, bioavailability and bioequivalence (generic drugs), pharmacodynamics, interactions (drug-drug, drug-food), evaluation and characterization of

biomarkers, proofs of concept, acceptability and preference studies (Coimbra Hurtado, Maria Jimena; Molina Perello, Pol).

- Follow-up studies in populations with the same or different characteristics: the elderly, obese volunteers, postmenopausal volunteers, patients with liver or kidney failure (Puntes Rodríguez, Montserrat).
- Collaboration with clinical services to conduct phase II or phase III studies (Garrido Sánchez, Maria Teresa).

SCIENTIFIC CHALLENGES

- Consolidate and strengthen leadership in this field in Spain, conserve relationships with the pharmaceutical industry at the national level, and strengthen and extend relations abroad with multinational enterprises and industries from other sectors.
- Broaden the range of questions addressed in research projects.
- Promote dissemination of our activity with a double objective: to return the knowledge generated to the society and to demystify research in humans, bringing it closer to the community so as to foster participation in clinical trials (particularly in specific sectors of the populations, such as the elderly).
- Set up educational activities related to the two main research lines, i.e., the application of Good Clinical Practices (GCPs) in clinical research (pathology and treatment) and the social (quality of life, prevention of accident risk) consequences.

ACTIVE & AWARDED GRANTS

- Antonijoan Arbos, Rosa. Investigación del potencial de nuevas moléculas para el tratamiento de enfermedades fibróticas (DEFIBER III). CPP2021-008747. Ministerio de Ciencia e Innovación (MICINN). Duration: 2022-2025. 243.536,44 €
- Antonijoan Arbos, Rosa. ERA4TB (European Accelerator of Tuberculosis Regime) project. ERA4TB GA 853989. European Comission. Duration: 2022-2025. 277.500,00 €
- Antonijoan Arbos, Rosa. Desarrollo clínico de una nueva terapia para el tratamiento de la narcolepsia (Adenowake). CPP2023-010422. Ministerio de Ciencia, Innovación y Universidades (MICIU). Duration: 2024-2027. 153.550,00 €
- Antonijoan Arbos, Rosa. Descubrimiento y desarrollo clínico de antagonistas no esteroideos del receptor de progesterona para el tratamiento de los fibromas uterinos (PR4UF). CPP2023-010778. Ministerio de Ciencia, Innovación y Universidades (MICIU). Duration: 2024-2027. 367.263,05 €
- Antonijoan Arbos, Rosa. Mejoras en la UiC para una Participación Accesible, Cómoda y Humana de Pacientes Vulnerables en la Investigación Clínica. UICM24/00039. Instituto de Salud Carlos III (ISCIII). Duration: 2025-2026. 1.406.625,00 €

SCIENTIFIC PRODUCTION

- Coimbra J, Puntes M, Molina P, Gich I, Antonijoan R, Gilaberte I, Arranz P, Sánchez C. Comparative inhibition by oral bilastine, parenteral dexchlorpheniramine, and a new bilastine parenteral (i.v. and i.m.) formulation of histamine-induced wheal and flare response: A randomised phase I trial. EUROPEAN JOURNAL OF PHARMACEUTICAL SCIENCES. 2024; 203:106900. DOI:10.1016/j.ejps.2024.106900. PMID:39265704. IF:4,300 (Q1/2D). Document type: Article.
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- Padró T, Santisteban V, Huedo P, Puntes M, Aguiló M, Espadaler J, Badimon L. Lactiplantibacillus plantarum strains KABP011, KABP012, and KABP013 modulate bile acids and cholesterol metabolism in humans. CARDIOVASCULAR RESEARCH. 2024; 120(7). DOI:10.1093/cvr/cvae061. PMID:38525555. IF:10,200 (Q1/1D). Document type: Article.

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- Ríos J, Sapena V, Marino Z, Bruix J, Forns X, Morros R, Reig M, Torres F, Pontes C. Incidence of Liver and Non-liver Cancers After Hepatitis C Virus Eradication: A Population-Based Cohort Study. Drugs-Real World Outcomes. 2024; 11(3). DOI:10.1007/s40801-024-00437-y. PMID:38874848. Document type: Article.
- Santisteban V, Muñoz N, López A, Puntes M, Badimon L, Padró T. Efficacy of Food Industry By-Product ß-Glucan/Chitin-Chitosan on Lipid Profile of Overweight and Obese Individuals: Sustainability and Nutraceuticals. Nutrients. 2024; 16(19):3420. DOI:10.3390/nu16193420. PMID:39408385. IF:4,800 (Q1/2D). Document type: Article.
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