



3.4.11 Translational Hepatology



Publications: 15 | **Q1:** 12

COMPOSITION

Francisco Javier García-Samaniego Rey.
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- **Marina Cambor Murube.** *Investigadora Predoctoral. Universidad Autónoma de Madrid*
- **Antonio Madejón Seiz.** *Investigador Postdoctoral. CIBERehd*
- **Antonio Oliveira Martín.** *Facultativo Especialista de Área en Hepatología. Hospital Universitario La Paz*
- **Miriam Romero Portales.** *Facultativo Especialista de Área en Gastroenterología. Hospital Universitario La Paz*

3 Research areas and groups

3.4. Large System Pathologies Area

STRATEGIC OBJETIVES

- The research group conducted by Dr. García-Samaniego has extensive experience in the study of liver diseases, focusing its research activity, in both, clinical and basic aspects. In recent years the group has developed its activity preferentially in the study of viral hepatitis. The expertise areas of the research group are the study of infections caused by the hepatitis viruses [hepatitis viruses B (HBV), C (HCV) and delta (HDV)] and the chronic liver disease related to HBV, HCV and HDV at a time in which highly efficient antiviral systems against HBV, and especially against HCV has been developed.
- In addition to complete the research lines, the global strategy of the group will be focused in maintaining the high level of collaboration, both with CIBERehd research groups and with external groups, as well as to increase of the cooperation ways with private enterprise.

RESEARCH LINES

Main research lines:

- Study of the epidemiological situation and optimization of the cascade of care for patients with infection by the hepatitis delta virus (HDV). Project in collaboration with the Hospital Clinic of Barcelona and Infanta Leonor of Madrid, and funded by the HDV DESCRIBE program sponsored by Gilead Scientific, S.A.
- Development of HCV micro-elimination strategies through the optimization and implementation of HCV detection and quantification systems at diagnostic points.
- Analysis of the role of epigenetic modifications induced by infection by hepatotropic viruses in the evolution of liver disease and the development of liver cancer, before and after antiviral treatment. Project performed in collaboration with the Department of Biochemistry of the Faculty of Medicine of the UAM and the Virology laboratory of the Molecular Biology Center "Severo Ochoa".
- Study of liver fibrosis progression factors in patients with metabolic hepatic steatosis.

Alternative lines of work:

- Study of the role of the intestinal microbiota as a prognostic factor for adverse effects in biological cancer therapy. Project developed in collaboration with the Department of Biochemistry of the Faculty of Medicine of the UAM.
- Study of the influence of pre-existing liver disease on the evolution of COVID.

RESEARCH ACTIVITY

Doctoral Theses

- **Cambior Murube M.** Variantes de aurora quinasa B: nuevos biomarcadores predictivos de desarrollo de carcinoma hepatocelular en pacientes infectados con VHC, tratados con antivirales de acción directa[dissertation]. Madrid: Universidad Autónoma de Madrid: 2024(31/10/2024). Director: Madejón Seiz A

Publications

- **Ampuero J, Aller R, Gallego-Durán R, Crespo J, Calleja JL, García-Monzón C, Gómez-Camarero J, Caballería J, Lo Iacono O, Ibañez L, García-Samaniego J, Albillos A, Francés R, Fernández-Rodríguez C, Maya-Miles D, Diago M, Poca M, Andrade RJ, Latorre R, Jorquera F, Morillas RM, Escudero D, Hernández-Guerra M, Pareja-Megía MJ, Banales JM, Aspichueta P, Benlloch S, Rosales JM, Turnes J, Romero-Gómez M.** The biochemical pattern defines MASLD phenotypes linked to distinct histology and prognosis. *J Gastroenterol.* 2024; 59(7): 586-597. Article. IF: 5.5; Q1
- **Ampuero J, Lucena A, Berenguer M, Hernández-Guerra M, Molina E, Gómez-Camarero J, Valdivia C, Gómez E, Casado M, Álvarez-Navascuez C, Jorquera F, García-Buey L, Díaz-González A, Morillas R, García-Retortillo M, Sousa JM, Pérez-Medrano I, Simón MA, Martínez J, Arenas J, Londoño MC, Oliveira A, Fernández-Rodríguez C.** Predictive factors for decompensating events in cirrhotic patients with primary biliary cholangitis under different lines of therapy. *Hepatology.* 2024; 80(4): 887-900. Article. IF: 15.8; D1
- **Brochado-Kith O, Rava M, Berenguer J, González-García J, Rojo D, Díez C, Hontañón V, Virseda-Berdices A, Ibáñez-Samaniego L, Llop-Herrera E, Oliveira A, Pérez-Latorre L, Barbas C, Fernández-Rodríguez A, Resino S, Jiménez-Sousa MA.** Altered blood microbiome in patients with HCV-related Child-Pugh class B cirrhosis. *J Infect Public Health.* 2024; 17(10): 102524. Article. IF: 4.0; Q1

J Infect Public Health. 2024; 17(10): 102524. Article. IF: 4.0; Q1

- **Colom J, Torrens M, Rodríguez-Cejas A, Aguilar I, Álvarez-Crespo R, Armenteros L, Ayala V, Cantero H, Casado MA, Crespo J, Estévez J, García-Samaniego J, Hernández-Guerra M, Mur C, Pérez-Bech E, Ricote M, Pineda JA.** Certification program of Addiction Centres for hepatitis C virus elimination in Spain. *HepCelentes Project. Adicciones.* 2024; 36(2): 129-44. Article. IF: 1.8; Q3

- **De Vincentis A, Ampuero J, Terracciani F, D'Amato D, Gerussi A, Cristofori L, Cazzagon N, Bonaiuto E, Floreani A, Calvaruso V, Cadamuro L, Degasperis E, Morgando A, Vanni E, Lleo A, Colapietro F, Alvaro D, Castellana A, Labanca S, Viganò M, Distefano M, Palitti VP, Ricci C, De Matthaeis N, Marzoni M, Gómez-Domínguez E, Montero JL, Molina E, García-Buey L, Casado M, Berenguer M, Conde I, Simón MA, Fuentes J, Costa-Moreira P, Macedo G, Jorquera F, Morillas RM, Presa J, Sousa JM, Gomes D, Santos L, Oliveira A, Hernández-Guerra M, Aburruza L, Santos A, Carvalho A, Uriz J, Gutierrez ML, Pérez E, Chessa L, Pellicelli A, Marignani M, Muratori L, Niro GA, Brunetto M, Ponziani FR, Pompili M, Marra F, Galli A, Mussetto A, Alagna G, Simone L, Bertino G, Rosina F, Cozzolongo R, Russello M, Baiocchi L, Saitta C, Terreni N, Zolfino T, Rigamonti C, Viganò R, Cuccorese G, Pozzoni P, Pedone C, Grasso S, Picardi A, Invernizzi P, Sacco R, Izzi A, Fernández-Rodríguez C, Vespasiani-Gentilucci U, Carbone M.** Development and Validation of a Scoring System to Predict Response to Obeticholic Acid in Primary Biliary Cholangitis. *Clin Gastroenterol H.* 2024; 22(10): 2062-74. Article. IF: 12.0; D1

- **Fernández C, Oliveira A.** Letter: Metabolic Dysfunction-Associated Steatotic Liver Disease in Primary Biliary Cholangitis-Friend, Foe or Red Herring? Authors' Reply. *Aliment Pharm Ther.* 2024; 60(11-12): 1643-44. Letter. IF: 6.7; D1

- **Fernández-Rodríguez CM, Gutiérrez ML, Oliveira A.** Editorial: Unravelling real-world impact of second-line therapies in primary biliary cholangitis-Time to change our targets? Authors' reply. *Aliment Pharm Ther.* 2024; 60(1): 91-2. Editorial Material. IF: 6.7; D1

- **Gómez E, Montero JL, Molina E, García-Buey L, Casado M, Fuentes J, Simón MA, Díaz-González A, Jorquera F, Morillas RM, Presa J, Berenguer M, Conde MI, Oliveira A, Macedo G, Garrido I, Hernández-Guerra M, Olivas I, Rodríguez-Taje S, Londoño M, Sousa JM, Ampuero J, Romero-González E, González-Padilla S, Escudero-García D, Carvalho A, Santos A, Gutiérrez ML, Pérez-Fernández E, Aburruza L, Uriz J, Gomes D, Santos L, Martínez-González J, Albillos A, Fernández-Rodríguez CM.** Longitudinal outcomes of obeticholic acid therapy in ursodiol-nonresponsive primary biliary cholangitis: Stratifying the impact of add-on fibrates in real-world practice. *Aliment Pharm Ther.* 2024; 59(12): 1604-15. Article. IF: 6.7; D1

- **Hernández-Pérez M, Riado D, Pena E, Méndez C, Pinedo F, Ramos P, Castillo P, Romero M, Fernández-Rodríguez C, Oliveira A.** The overlap with metabolic dysfunction-associated steatotic liver disease negatively affects outcomes of primary biliary cholangitis. *Aliment Pharm Ther.* 2024; 60(5): 613-9. Article. IF: 6.7; D1

- **Moragrega AB, Busca C, Apostolova N, Oliveira A, Martín-Carbonero L, Valencia E, Moreno V, Bernardino JI, Abadía M, González-García J, Esplugues JV, Montes ML, Blas-García A.** Rilpivirine Activates STAT1 in Non-Parenchymal Cells to Regulate Liver Injury in People Living with HIV and MASLD. *Biomedicines.* 2024; 12(7): 1454. Article. IF: 3.9; Q2

- **Oliveira A, Jimenez V.** Hemophilia and hepatology, back to the future. *Rev Esp Enferm Dig.* 2024; 116(4): 179-81. Editorial Material. IF: 4.0; Q1

- **Razavi-Shearer DM, Buti M, Tacke F, Terrault NA, Zeuzem S, Abbas Z, Aghemo A, Akarca US, Al Masri NM, Alalwan AM, Blomé MA, Aleman S, Alghamdi AS, Alghamdi M, Alghamdi S, Al-Hamoudi WK, Ali E, Aljumah AA, Altraif IH, Amarsanaa J, Asselah T, Baatarkhuu O, Babameto A, Ben-Ari Z, Berg T, Biondi MJ, Braga WSM, Brandao-Mello CE, Brown RS, Brunetto MR, Cabezas J, Cardoso M, Chan HLY, Cheinquer H, Chen CJ, Chen PJ, Chien CH, Child H, Chuang WL, Garza LEC, Coco B, Coffin CS, Coppola N, Cornberg M, Craxi A, Crespo J, Cuko L, De Ledinghen V, Duberg AS, Etzion O, Ferraz MLG, Ferreira PRA, Fornis X, Foster GR, Fung J, Gaeta GB, García-Samaniego J, Genov J, Gheorghe LS, Gholam PM, Gish RG, Glenn J, Goldis A, Hamid SS, Hercun J, Hsu YC, Hu CC, Huang JF, Idilman R, Jafri WSM, Janjua N, Jelev D, Jerkeman A, Jia JD, Kåberg M, Kaita KDE, Kao JH, Khan AG, Kim DY, Kondili LA, Lagging M, Lampertico P, Lázaro P, Lazarus J, Lee MH, Lim YS, Lobato CMO, Macedo G, Marinho RT, Marotta PJ, Martins A, Mendes-Correa MC, Méndez-Sánchez N, Navas MC, Ning Q, Örmeci N, Orrego M, Osiowy C, Pan CQ, Pessoa MG, Piracha ZZ, Pop C, Ramos JAP, Qureshi H, Raimondo G, Ramji A, Razavi-Shearer K, Ribeiro S, Ríos-Hincapié CY, Rodríguez M, Rosenberg WMC, Roulot D, Ryder SD, Saeed U, Safadi R, Sanai FM, Sánchez-Avila JF, Santantonio TA, Sarrazin C, Seto WK, Shouval D, Simonova MY, Tanaka J, Tergast TL, Tsendsuren O, Valente C, Villalobos-Salcedo JM, Voeller AS, Waheed Y, Wong GLH, Wong VWS, Wu JC, Yang H, Yip TCF, Yu ML, Yuen MF, Yurdaydin C, Zuckerman E, Razavi HA.** Adjusted estimate of the prevalence of hepatitis delta virus in 25 countries and territories. *J Hepatol.* 2024; 80(2): 232-42. Article. IF: 33.0; D1
- **Romero-Gutiérrez M, Alonso P, Berenguer M,**

3 Research areas and groups

- Olveira A, González-Diéguez ML, Iruzubieta P, Masnou H, Delgado M, Hernández-Guerra M, Lorente S, Lázaro M, Moreno-Planas JM, Gonzalez C, Fernández-Alvarez P, Cuenca F, Gómez J, García-Villareal L, Rodríguez O, Mariño Z.** Reproductive and pregnancy control in Wilson disease patients in Spain. *Eur J Gastroen Hepat.* 2024; 36(11): 1340-5. Article. IF: 1.8; Q3
- Ruiz-Cobo JC, Llaneras J, Forn X, Moya AG, Amiel IC, Arencibia A, Diago M, García-Samaniego J, Castellote J, Llerena S, Rodríguez-Seguel E, Mateos B, Rodríguez M, Zabal JMR, Fernández I, Calleja JL, Morillas RM, Montoliu S, Andrade RJ, Aranda EB, Hernández-Guerra M, Mate CJ, Gonzalez-Santiago JM, de Cuenca B, Bernal-Monterde V, Delgado M, Turnes J, Lens S, Buti M.** Real-life effectiveness of sofosbuvir/velpatasvir/voxilaprevir in hepatitis C patients previously treated with sofosbuvir/velpatasvir or glecaprevir/pibrentasvir. *Aliment Pharm Ther.* 2024; 60(2): 201-11. Article. IF: 6.7; D1
- Spigarelli IM, Pillado B, Vincent D, Poza J, Abadía M, Ruiz-Fernández G, Marin E, Castillo P, Polo B, Olveira A.** Low phospholipid-associated cholelithiasis syndrome, a not uncommon cause of biliary problems and hospital admissions. *Rev Esp Enferm Dig.* 2024; 116(10): 532-8. Article. IF: 4.0; Q1

Research projects

- García-Samaniego Rey J.** Búsqueda activa de pacientes con hepatitis crónica viral (VHC Y VHD) no diagnosticada, en población general, desde los Centros de salud de la Comunidad de Madrid (2023.263). Gilead Sciences. 2022-2024. **Managment centre:** FIBHULP
- García-Samaniego Rey J.** Estudio epidemiológico y molecular de la infección por vhd en una gran área urbana de España. Optimización de la cascada de atención (PI22/00849). ISCIII. 2023-2025. **Managment centre:** ISCIII

- García-Samaniego Rey J.** Study of the epidemiological situation and optimization of the cascade of care for patients with infection by the hepatitis delta virus (HDV). HDV Describe (EHD22PE02). Gilead Sciences. 2023-2025. **Managment centre:** CIBER

Clinical trials

- "García-Samaniego Rey J.** estudio fase ii, simple ciego, aleatorizado, controlado e internacional para evaluar la seguridad, reactogenicidad, eficacia y respuesta inmune tras el tratamiento secuencial con un oligonucleótido antisentido (aso) para la hepatitis b crónica (hbc) seguido de inmunoterapia dirigida contra la hepatitis b crónica (hbcit) en pacientes con hbc en tratamiento con análogos de nucleós(t)idos (an). **Type/Phase:** II **Sponsored by:** Glaxosmithkline S.A. **Signature date:** 13/06/2024"
- "García-Samaniego Rey J.** multicentre, observational study in patients with liver cirrhosis who have been hospitalised for the first time for hepatic decompensation. Estudio multicéntrico y observacional en pacientes con cirrosis hepática que hayan sido hospitalizados por primera vez debido a descompensación hepática. rtx001-01s. **Type/Phase:** OTROS **Sponsored by:** Resolution Therapeutics Ltd. **Signature date:** 18/07/2024"
- Olveira Martín A.** a phase III double-blind, randomised, placebo-controlled trial to evaluate liver-related clinical outcomes and safety of once weekly injected survodutide in participants with compensated nonalcoholic steatohepatitis/metabolic dysfunction associated steatohepatitis (nash/mash) cirrhosis. **Type/Phase:** III **Sponsored by:** Boehringer Ingelheim International GMBH **Signature date:** 21/11/2024
- Olveira Martín A.** a phase iiib randomised, parallel-group, double-blind, placebo-controlled, two-arm study to evaluate the effect of elafibranor

80 mg on normalisation of alkaline phosphatase in adult participants with primary biliary cholangitis (pbc) and inadequate response or intolerance to ursodeoxycholic acid.

Type/Phase: IIIB

Sponsored by: Ipsen Bioscience Inc.

Signature date: 24/05/2024

- Olveira Martín A.** a randomised, double-blind, placebo-controlled, multicentre, phase iii trial evaluating long-term efficacy and safety of survodutide weekly injections in adult participants with noncirrhotic non-alcoholic steatohepatitis/metabolic associated steatohepatitis (nash/mash) and (f2)-(f3) stage of liver fibrosis.

Type/Phase: IIIa

Sponsored by: Boehringer Ingelheim International GMBH

Signature date: 21/11/2024

- Olveira Martín A.** ensayo de fase iii multicéntrico, aleatorizado, doble ciego, comparativo con placebo, de 48 semanas de duración, para evaluar la eficacia y la seguridad de survodutide administrada por vía subcutánea en participantes con sobrepeso u obesidad y esteatohepatitis no alcohólica (ehna) presunta o confirmada.

Type/Phase: III

Sponsored by: Boehringer Ingelheim International GMBH

Signature date: 30/04/2024

- Olveira Martín A.** estudio de fase 2a, aleatorizado, doble ciego y controlado con placebo para evaluar la eficacia y la seguridad de efinopegdutida (mk-6024) en adultos con cirrosis compensada secundaria a esteatohepatitis asociada a disfunción metabólica.

Type/Phase: IIa

Sponsored by: Merck Sharp & Dohme LLC

Signature date: 17/08/2024

- Olveira Martín A.** estudio en fase ii, multicéntrico, con doble enmascaramiento, aleatorizado, comparado con placebo y de extensión a largo plazo sin enmascaramiento para evaluar la seguridad y la eficacia de elafibranor en participantes adultos con colangitis esclerosante primaria (cep).

3 Research areas and groups

3.4. Large System Pathologies Area

Type/Phase: II

Sponsored by: Ipsen Bioscience Inc.

Signature date: 13/03/2024

- Olveira Martín A.** registro observacional de enfermedad y resultados clínicos de pacientes con deficiencia de lipasa ácida lisosomal (lal) (enfermedad de wolman y enfermedad por almacenamiento de ésteres de colesterol) y portadores del trastorno.

Type/Phase: No EPA

Sponsored by: Pharmaceuticals Inc.

Signature date: 12/01/2024

- Romero Portales M.** optimización de las exploraciones mediante vcte en el bazo con fibroscan.

Type/Phase: PRODUCTO SANITARIO

Sponsored by: Echoscens S.A.

Signature date: 02/05/2024

Patents and trademarks

- Castán P, Gil-García AI, Madejón A, Sainz-Martínez E, Montoya JJ, Ouahid Younes, inventors; MIRNAX BIOSSENS S.L., assignee.** Bivalent reverse primers Application number (EPO): 20382336.4-1118. 2020 April 24.
- Madejón A; inventor; Agile Life Sciences LTD, assignee.** Kit and methods Application number: GB202010372.A. 2020 July 6.