Department of Medicine and Research Laboratory of Internal Medicine
National Expertise Center of Greece in Autoimmune Liver Diseases
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Clinical studies

1. An open label long-term study to evaluate the safety and tolerability of seladelpar in subjects with pritmary biliary cholangitis (CB8025-31731)
2. A 52-week, placebo-controlled, randomised, Phase 3 study to evaluate the safety and efficacy of seladelpar in subjects with primary biliary cholangitis and an inadequate response to or an intolerance to UDCA (CB8025-31735)
3. Tenofovir alafenamide in chronic hepatitis B: A Hellenic multicenter ReAl-life Clinical Study (HERACLIS-TAF)
4. Biomarkers for liver inflammation and their impact on the prognossis of PSC -Particularly, the impact of serum IgG and ALT levels on disease progression will be analysed, then impact of immunosuppressive treatment (International PSC Study Group)
5. Screening and management of dominant strictures in PSC: a multicenter cohort analysis (International PSC Study Group)
6. Surveillance strategies for HB malignancy (International PSC Study Group)
7. Novel technologies for surveillance and characterization of Extended-spectrum β-lactamase and Carbapenemase producing Enterobacteriaceae, in humans and animals (CARBATECH)
8. Prospective observational study to assess the risk factors, clinical management and outcomes of hospitalized patients with serious infections caused by carbapenem-resistant Enterobacteriaceae and Acinetobacter baumannii (EURECA)
9. Η αποτελεσματικότητα και η ασφάλεια του αντιβιοτικού Κεφταζιδίμη-Αβιμπακτάμη (Zavicefta) στη θεραπεία ενηλίκων ασθενών με νοσοκομειακή λοίμωξη από εξαιρετικώς ανθεκτικά στα αντιβιοτικά (XDR) Gram αρνητικά βακτήρια
10. A Phase 2, Double-Blind, Randomized, Parallel-Group Study Evaluating the Efficacy, Safety, and Tolerability of Obeticholic Acid, Administered Alone or in Combination with Bezafibrate, in Subjects with Primary Biliary Cholangitis who had an Inadequate Response or who were Unable to Tolerate Ursodeoxycholic Acid (INTERCEPT 747-213)
11. "A prospective, randomized, open-label, comparative study to assess the efficacy, safety and tolerability of aztreonam-avibactam (atm-avi) and best available therapy for the treatment of serious infections due to multi-drug resistant gram- negative bacteria producing metallo-β-lactamase (mbl)
12. Epigenetics in autoimmune liver diseases
13. Long-term outcome and risk stratification in autoimmune hepatitis – an international, multicenter retrospective observational study
14. Biomarkers for liver inflammation and their impact on the prognosis of PSC (International PSC Study Group)
15. Screening and management of dominant strictures in PSC: a multicenter cohort analysis (International PSC Study Group)
16. Surveillance strategies for hepatobiliary malignancy (International PSC Study Group)
17. Εφαρμογή καινοτόμων τεχνολογιών για τη διερεύνηση και χαρακτηρισμό Εντεροβακτηριοειδών που παράγουν ευρέως φάσματος β-λακταμάσες και καρβαπενεμάσες σε ανθρώπους και ζώα (CARBATECH)
18. Prospective observational study to assess the risk factors, clinical management and outcomes of hospitalized patients with serious infections caused by carbapenem-resistant Enterobacteriaceae and Acinetobacter baumannii
19. Η αποτελεσματικότητα και η ασφάλεια του αντιβιοτικού Κεφταζιδίμη - Αβιμπακτάμη (Zavicefta) στη θεραπεία ενηλίκων ασθενών με νοσοκομειακή λοίμωξη από εξαιρετικώς ανθεκτικά στα αντιβιοτικά (XDR) Gram αρνητικά βακτήρια
20. A prospective, randomized, open-label, comparative study to assess the efficacy, safety and tolerability of aztreonam-avibactam (atm-avi) and best available therapy for the treatment of serious infections due to multi-drug resistant gram- negative bacteria producing metallo-β-lactamase (mbl)

21. EU-Wide Cross-sectional Observational Study of Lipid-Modifying Therapy Use in Secondary and Primary Care DA VINCI (20150333)
22. GSN000300 - A Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Assess the Efficacy and Safety of Oral GKT137831 in Patient with Primary Biliary Cholangitis Receiving Ursodeoxycholic Acid and with Persistently Elevated Alkaline Phosphatase
23. A single arm, open-label study to evaluate the efficacy and safety of Glecaprevir (GLE) / Pibrentasvir (PIB) in treatment naïve adults with chronic hepatitis C virus (HCV) genotype 1, 2, 4, 5, or 6 infection and compensated cirrhosis (M16-135 - ABBVIE)
24. A European, observational, three-year cohort comparative study on the safety of the fixed-dose combination pravastatin 40mg/fenofibrate 160 mg (Pravafenix®) versus statin alone in real clinical practice. (POSE: Pravafenix® Observational Study in Europe)
25. «Phase IIA exploratory study of oral Milciclib Maleate in patients with Unresectable or Metastatic Hepatocellular Carcinoma»
26. Natural History - Portal Vein Thrombosis Study (Greek multicentre Study)
27. COMBACTE-CARE-Combatting bacterial resistance in Europe - Carbapenem resistance
28. Μία διπλή-τυφλή τυχαιοποιημένη μελέτη αξιολόγησης και αποκατάστασης της ανοσιακής διαταραχής στις σοβαρές λοιμώξεις και στη σήψη: Η μελέτη PROVIDE
29. Διερεύνηση της αποτελεσματικότητας και της ασφάλειας τριών δόσεων υποδορίως χορηγούμενης semaglutide, άπαξ ημερησίως, έναντι εικονικού φαρμάκου σε ασθενείς με μη αλκοολική στεατοηπατίτιδα NN9931-4296
30. AIH and NAFLD/NASH: i) Do all NASH patients have truly only NASH? ii) NAFLD/NASH in AIH: important player or innocent bystander?
31. Diagnostic performance of FíbroMeter® (ECHOSENS) in the assessment of liver fibrosis alone or in combination with FibroScan® (ECHOSENS)
32. An observational long-term safety and efficacy follow-up study of subjects who have previously received RG-101 (RG101-05)
33. Assessment of IAIHG criteria for PSC-AIH overlap (International PSC Study Group)
34. “Moving from biochemically early to advanced PBC: are there any prognostic factors?” (Global PBC Study Group)
35. A multi-center, parallel group, open-label, phase 2 study to evaluate the efficacy and safety of a signle subcutaneous injection of RG-101 combined with Oral GSK2878175 taken once daily for 6, 9, or 12 weeks in treatment naïve, genotype 1 and 3, chronic hepatitis C patients (RG101-04).
36. Ανοικτή τυχαιοποιημένη κλινική μελέτη εκτίμησης της ασφάλειας και αποτελεσματικότητας της μυκοφαινολάτης σε σχέση με την αζαθειοπρίνη για την επαγωγή και διατήρηση της ανταπόκρισης μετά την πλήρη διακοπή της θεραπείας σε πρωτοθεραπευόμενους ασθενείς με αυτοάνοση ηπατίτιδα.
37. "Καταγραφή ασθενών με αυτοάνοση ηπατίτιδα" μία αναδρομική και προοπτική, μη παρεμβατική μελέτη καταγραφής ασθενών με αυτοάνοση ηπατίτιδα, στα πλαίσια συμμετοχής σε μία πανελλήνια πολυκεντρική καταγραφή ασθενών με αυτοάνοση ηπατίτιδα, η οποία διεξάγεται υπό το συντονισμό της "Ελληνικής Εταιρείας Μελέτης της Αυτοάνοσης Ηπατίτιδας της Ελληνικής Εταιρείας Μελέτης Ήπατος"
38. Μετεγκριτική μελέτη παρατήρησης με κωδικό P15-842 και τίτλο "Δεδομένα καθημερινής κλινικής πράξης για τη δραστικότητα της παριταπρεβίρης/r - ομπιτασβίρης ± ντασαμπουβίρης ± ριμπαβιρίνης σε ασθενείς με χρόνια ηπατίτιδα C - Μελέτη Παρατήρησης στην Ελλάδα (Μελέτη OPAL)" (ABBVIE)
39. Διερεύνηση του μεταβολικού προφίλ του αίματος ασθενών με αυτοάνοσα νοσήματα του ήπατος (ANH) με φασματοσκοπία Πυρηνικού Μαγνητικού Συντονισμού (NMR): διερεύνηση της χρησιμότητάς του στη διάγνωση, παρακολούθηση και πρόγνωση των ANH
40. Προγνωστικοί παράγοντες διατήρησης της ύφεσης και ανοσολογικές μεταβολές σε ασθενείς με HBeAg-αρνητική χρόνια ηπατίτιδα Β που διακόπτουν αποτελεσματική μακροχρόνια θεραπεία με αντιικά.
41. A randomized, multi-center, phase 2 study to evaluate safety and efficacy of subcutaneous injections of RG-101 in combination with oral agents in treatment naïve, genotype 1 and 4, chronic hepatitis C patients (RG101-02).
42. Comparison of leishmania species in human and dogs and their geographic distribution in Thessaly
43. Biomarker Signature of Stroke Aetiology Study: The BIOSIGNAL-Study
44. A phase IIIb/IV randomized, controlled, open label, parallel group study to compare the efficacy of vancomycin therapy to extended duration fidaxomicin therapy in the sustained clinical cure of Clostridium difficile Infection in an older population.

45. A phase IV, blood sample collection study for exploratory evaluation of the association of signle nucleotide polymorphisms with treatment responses from subjects with HBe-Ag positive or negative chronic hepatitis B, who received therapy for hepatitis B with peginterferon alpha-2a 40kD ± Nucleos(t)ide analogue (Sponsor: F-Hoffmann-La Roche Ltd)

46. Καταγραφή ασθενών με αυτοάνοση ηπατίτιδα στους οποίους η νόσος εμφανίστηκε κατά την παιδική ηλικία (<18 έτη). Στην πολυκεντρική αυτή μελέτη γίνεται αποτύπωση του φαινοτύπου της νόσου και συσχέτιση με γονιδιακές μελέτες. Πραγματοποιείται σε παγκόσμιο επίπεδο υπό το συντονισμό της Giorgina Mieli-Vergani (Professor of Paediatric Hepatology, King's College Hospital, NHS Foundation Trust)

47. Anti-α-actinin antibodies cross-react with anti-ssDNA antibodies in active autoimmune hepatitis

48. Anti-α actinin antibodies as new predictors of response to treatment in autoimmune hepatitis type 1

49. Simplified criteria for the diagnosis of autoimmune hepatitis (International Autoimmune Hepatitis Group)

50. Comparison of simplified score with the revised original score for the diagnosis of autoimmune hepatitis: a new or a complementary diagnostic score?

51. The revised international autoimmune hepatitis score in chronic liver diseases including autoimmune hepatitis/overlap syndromes and autoimmune hepatitis with concurrent other liver disorders

52. Hemopoietic progenitor cells and bone marrow stromal cells in patients with autoimmune hepatitis type 1 and primary biliary cirrhosis (Υπουργείο Παιδείας – Πυθαγόρας ΙΙ)

53. Cytokines production is distinct in bone marrow cultures from patients with autoimmune hepatitis type 1 and primary biliary cirrhosis (Υπουργείο Παιδείας Πυθαγόρας ΙΙ)

54. Markers of cell activation and apoptosis in bone marrow mononuclear cells of patients with autoimmune hepatitis type 1 and primary biliary cirrhosis (Υπουργείο Παιδείας – Πυθαγόρας ΙΙ)

55. An international, multicenter, prospective, observational study to assess the epidemiological, humanitarian and economic outcomes of treatment of chronic hepatitis C (Sponsor: ABBVIE)

56. Evaluating PCSK9 Binding antibody influence on cognitive health in high cardiovascular risk subjects (EBBINGHAUS).

57. "Use of boceprevir in addition to standard Pegylated Interferon alpha and Ribavirin regimen in genotype 1 Chronic Hepatitis C treatment-experienced patients in the Greek routine clinical practice"

58. "OPTIMIS - Outcomes of HCC patients treated with TACE followed or not followed by sorafenib and the influence of timing to initiate sorafenib" (BAY 43-9006, Sorafenib / study identifier: 16560/NX 1301)

59. A double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-Cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease

60. LASTRO

61. Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Subjects With Elevated Risk (FOURIER)

62. GLORIA-AF

63. Blood Pressure Variability in Acute Ischemic Stroke (PREVISE)

64. European, multi-centre, prospective bi-annual point prevalence study of Clostridium difficile Infection in hospitalized patients with Diarrhoea (EUCLID)

65. "Non-Interventional Cohort Study on the Utilization and Impact of Dual and Triple Therapies Based on Pegylated Interferon for the Treatment of Chronic Hepatitis C" (MV25599)

66. Hepatitis Delta International Network

67. ARISTEIDIS (The Antimicrobial Chemoprophylaxis for Ischemic Stroke in Macedonia-Thrace Study)

68. Mechanisms of signal transduction and gene expression in hepatocellular carcinoma - THALIS (in collaboration with Department of Biology, Aristotle University of Thessaloniki)

69. "An international, Multi-Center Study Evaluating the Correlation of IL28B Genotypes with Chronic Hepatitis C Disease Characteristics and Patient Demographics" (MV25600)

70. "A phase III, randomized, double-blind trial to evaluate the efficacy, safety and tolerability of TMC435 vs telaprevir, both in combination with Peg-IFNα-2a and ribavirin, in chronic hepatitis C genotype-1 infected subjects who were null or partial responders to prior PegIFNα and ribavirin therapy" (TMC435HPC3001)

71. "Study of polymorphisms of Toll-like Receptor (TLR)-4 and tumor necrosis factor-α (TNF-α) in patients with brucellosis. 4th Department of Internal Medicine, University Hospital ATTIKON, School of Medicine National and Kapodistrian University of Athens.

72. Prospective, multicenter, non-interventional epidemiological study of infectious endocarditis in Greece. Hellenic Society of Chemotherapy

73. Multicenter, Open-Label, study of Telaprevir in Combination With Peginterferon Alfa and Ribavirin in Genotype 1 Chronic Hepatitis C Subjects With Severe Fibrosis and Compensated Cirrhosis (VX-950HEP3002)

74. ENOS

75. “In vitro study for telavancin activity against staphylococcal species and correlation with phenotypes of resistance in Greece”. Department of Microbiology, Larissa Medical School, University of Thessaly, 4th Department of Internal Medicine, University Hospital ATTIKON, School of Medicine National and Kapodistrian University of Athens.

76. EU-CORE: European registry of outcome and experience from Cubicin use for the treatment of severe infections from gram positive bacteria (CCBC134A2403)

77. «Hepatitis B, Hepatitis C and HIV Clinical Sample Collection study» (BB-ID-034)

78. PSC Genetics Study (IMMUNOCHIP Project)

79. PBC Genetics Study

80. Study of immunological responses in patients with sepsis, severe sepsis and septic shock. Hellenic Society of Chemotherapy.

81. Multicenter (23 centers) non-interventional study Phase IV: Prognostic factors of long-term response to treatment with pegylated interferon alpha-2a in HBeAg negative chronic hepatitis B patients (PERSEAS)

82. A multicenter, Phase 3b, randomized, double-blind, double-dummy study, evaluating the antiviral efficacy, safety, and tolerability of Tenofovir Disoproxil Fumarate monotherapy versus Emtricitabine plus Tenofovir DF fixed-dose combination therapy in subjects with chronic hepatitis B who are resistant to lamivudine

83. A multicenter, double blinded study on Tenofovir vs Adefovir in the treatment of naïve patients with chronic anti-HBe positive hepatitis B.

84. A multicenter, double blinded study in patients with chronic hepatitis C who are non-responders to prior peginterferon-a or peginterferon-a + ribavirin therapy comparing treatment with thymosin a1 + peginterferon-a-2a plus ribavirin with peginterferon-a-2a + ribavirin + placebo

85. Phase 3b, open-label program of adefovir dipivoxil in the treatment of patients with lamivudine-resistant chronic hepatitis B who have limited treatment options (GS-01-550)

86. Clinical significance of hepatitis B virus DNA levels in HBeAg-negative, HBV-genotype D-infected patients.

87. A multicenter randomized study comparing the efficacy of adefovir dipivoxil vs pegylated interferon-alfa-2a plus placebo vs adefovir dipivoxil plus pegylated interferon-alfa-2a for the treatment of chronic delta hepatitis