

**Pediatric AIDS Clinical Trials Group
JHU Protocol Enrollment
1986 – 2006**

PEDIATRIC AIDS CLINICAL TRIALS GROUP - Site 3701 Johns Hopkins University			
Protocol Number	Phase	Title	JHU Enrollment
43		A Multicenter Trial to Evaluate Oral AZT in the Treatment of Children with Symptomatic HIV Infection	7
49	1	A Multicenter Phase I Trial to Evaluate the Safety and Pharmacokinetics of Intravenous and Oral AZT in Infants with Perinatal HIV Exposure	6
51	2	A Double-Blind, Placebo-Controlled Trial to Evaluate IVIG in Children with Symptomatic HIV Infection Receiving AZT	7
76	3	A Phase III Randomized, Placebo-Controlled Trial to Evaluate the Efficacy, Safety and Tolerance of Zidovudine for the Prevention of Maternal-Fetal HIV Transmission	11
128	2	A Randomized Blinded Trial to Evaluate the Safety and Tolerance of High Versus Low Dose Zidovudine Administered to Children with Human Immunodeficiency Virus	15
144	2	Randomized Comparative Trial of Two Doses of 2'3'-Dideoxyinosine (ddl) in Children with Symptomatic HIV Infection Who are Either Unresponsive to Zidovudine and/or Who are Intolerant to Zidovudine	4
152	2	Randomized Comparative Trial of Zidovudine (ZDV) Versus 2'3'Dideoxyinosine (ddl) Versus ZDV Plus ddl in Symptomatic HIV-Infected Children	17
182	3	Phase III Study to Evaluate the Safety, Tolerance and Efficacy of Early Treatment with Zidovudine (ZDV) in Asymptomatic Infants with HIV Infection	0
185	3	A Phase III Randomized, Double-Blind Controlled Study of the Use of HIVIG for the Prevention of Maternal-Fetal HIV Transmission in Pregnant Women Receiving Zidovudine	4
218	1	A Placebo Controlled, Phase I Clinical Trial to Evaluate the Safety and Immunogenicity of Recombinant Envelope Proteins of HIV-1 gp160 and gp120 in Children \geq 1 Month Old with Asymptomatic HIV Infection	2
219	Obs	Pediatric Late Outcomes Protocol.	30
219C	Obs	Pediatric Late Outcomes Protocol	69
225	2	A Phase II Comparative Study of Seroconversion of Single-Dose and Two-Dose Measles Vaccination in HIV-Infected and HIV-Uninfected Children: A Multicenter Trial of the AIDS Clinical Trials Group	0
230	1	A Phase I Study to Evaluate the Safety and Immunogenicity of Recombinant HIV-1 Envelope Antigen in Children Born to HIV Infected Mothers	7
235	1	Active Immunization of HIV-1 Infected, pregnant Women, with CD4 Lymphocyte Counts \geq 400/mm ³ : A Phase 1 Study of Safety and Immunogenicity of MN rgp 120/HIV-1 Vaccine	4

245	2	A Comparative Study of Combination Antiretroviral Therapy in Children and Adolescents with Advanced HIV Disease	13
247	2	A Randomized, Double-Blind, Controlled Study of an Increased Caloric Density Infant Formula and its Effect on Growth and Nutritional Status in HIV-Infected Infants.	32
254	2 & 3	Rand. Phase II/III, Two-Armed Study of Micronized-Atovaquone and Azithromycin (AT/AZ) as Compared to (TMP/SMX) in the Prevention of Serious Bacterial Infections When Used in Children Aged 2-19 Years with HIV Infection.	4
265	1 & 2	Phase I/II Study of Safety and Immunogenicity of Live-Attenuated Varicella Vaccine (Varivax) in HIV-Infected Children	3
273	1 & 2	A Phase I/II Study of HIVIG in Slowing Progression of Disease in HIV-Infected Children	0
288	Obs	Follow-up of Women Participating in ACTG 076	3
292	1 & 2	A Double Blind, Placebo Controlled Trial of the Safety and Immunogenicity of a Seven Valent Pneumococcal Conjugate Vaccine in Presumed HIV-Infected Infan	0
300	2	A Randomized Comparative Study of Combined Zidovudine-Lamivudine (3TC) vs. the Better of ddl Monotherapy vs. Zidovudine Plus ddl in Symptomatic HIV-1 Infected Children	0
310	1	A Phase 1A Single Dose Pharmacokinetics and Safety Study of the Oral Antiviral Compound, 9-[2-(bispivaloyloxymethyl)phosphonylmethoxyethyl]adenine (bis-POM PMEA) (adefovir dipivoxil) in Children with HIV-1 Infection	3
316	3	A Phase III Randomized, Double Blinded Study of Nevirapine for the Prevention of Maternal-Fetal Transmission in Pregnant HIV-Infected Women	14
353	1	A Phase I Trial of the Safety and Pharmacokinetics of Oral Nelfinavir (Viracept) Co-Administered with ZDV and 3TC in HIV Seropositive Pregnant Women and Their Infants	4
356	1 & 2	Early Intensive Antiretroviral Combination Therapy in HIV-1 Infected Infants.	2
366	1 & 2	A Phase I/II Master Protocol of Novel Antiretroviral Combination Therapies in Antiretroviral Experienced Children with Rapidly Progressing or Advanced HIV Disease (RAD).	3
367	Obs	Chart Abstraction of HIV-Infected Pregnant Women and Their Infants Receiving Care or Consultation at Study Sites.	60
377	1 & 2	A Phase I/II Randomized, Multicenter Protocol Comparing Four Antiretroviral Regimens Containing Combinations of Protease Inhibitors, NRTIs and an NNRTI.	5
382	1 & 2	A Phase I/II, Open-Label, AUC-Controlled Study to Determine the Pharmacokinetics, Safety, Tolerability, and Antiviral Activity of DMP 266 in Combination with Nelfinavir in Children	0
391	2	Use of a live-attenuated varicella-zoster virus (VZV) vaccine to boost immunity to VZV in HIV-Infected children previously infected with varicella.	0
397	2	Randomized Trial of Two Saquinavir-Containing Combination Treatment Regimens in Children with HIV Infecti	2

403	2	Randomized, Multicenter Protocol Evaluating Two Antiretroviral Regimens Containing Combinations of Protease Inhibitors, NRTIs and NNRTI <PRAM 3>.	0
707	1	Durability of Cell-Mediated and Humoral Immune Responses to Vaccine Antigens in Children Born to HIV-Infected Mothers: A Substudy of ACTG 230	2
725	1	ACTG 725 is a Pharmacokinetic Substudy of Nelfinavir Tablets Given to Children < 30 kg in ACTG 377	2
727		ACTG 727 is a Substudy of ACTG 377: Immunology Substudy of DTaP Vaccine Given to Children 2-9 Years of Age with Negative Tetanus Antibody Titers in ACTG 377	1
852		ACTG 852 is a substudy of ACTG 152. Analysis of Subject Samples for Determination of SCD8, Neopterin, and Beta-2 Microglobulin.	9
953	Obs	Nested Study: Follow patients who have CD4 counts less than 50 and are taking MAC prophylaxis	2
P1006		The Effects of Highly Active Antiretroviral Therapy (HAART) on the Recovery of the Immune Function in a Population on HIV-Infected Children and Young Adults	1
P1009		Mononuclear Cell Phenotyping in Normal Children	1
P1010		Effect of Antiretroviral Therapy on Body Composition in HIV-Infected Children	1
P1015	2	Intensification of HIV-Specific CD4 and CD8 Activity by Cycling Highly Active Antiretroviral Therapy (HAART) in Pediatric/Adolescent Patients with < 50 HIV RNA copies/mL.	1
P1020a	1 & 2	A Phase I/II Open Label Pharmacokinetic and Safety Study of A Novel Protease Inhibitor (BMS 232632) in Combination Regimens in ART Naive and Experienced HIV-infected Infants, Children and Adolescents	2
P1028		Hepatitis C Prevalence in HIV-Infected Children Substudy to PACTG 219C	12
P1030	1 & 2	A Phase I/II Study of Lopinavir/Ritonavir in HIV-1 Infected Infants <6 Months of Age.	2
P1034	2	Comparative Trial of Protease-Containing and Protease-Sparing HAART Regimes in HIV-Infected Adolescents with an Evaluation of Therapeutic Drug Monitoring.	1
P1038	1 & 2	A Phase I/II Safety, Tolerability, and Phamacokinetic Study of High Dose Lopinavir/Ritonavir with or without Saquinavir in HIV infected Pediatric Subjects Previously Treated With Protease Inhibitors.	0
P1042S		Cognitive, Behavioral, and Psychosocial Correlates of Medication Adherence in Children and Adolescents with HIV-1 Infection	1
P1045		Prevalence Of Morphologic And Metabolic Abnormalities In Vertically HIV Infected And Uninfected Children And Adolescents	5
P1057	1 & 2	A Phase I/II Randomized Trial of the Safety and Immunogenicity of Cold Adapted Influenza Vaccine (FluMist) In HIV-Infected Children.	2
42/51		Total	376