PSG
PARKINSON STUDY GROUP

PSG Data Base Inventory

chronological with the most recent trial listed at the top
(updated January 2008)

PRECEPT (Ira Shoulson PI, Cephalon, Inc. sponsor) was a study of 806 individuals with early, untreated PD who were randomized to 1 of 3 dosages of CEP-1347 or placebo and were followed for 2 years. The primary outcome measure was the need to initiate levodopa therapy. UPDRS scores and quality of life scales were also completed. The study was terminated early because of futility and full 2 year data is not available on all subjects.

PRESTO (Ira Shoulson PI, Teva Pharmaceutical Industries, Ltd. sponsor) was a study of 472 advanced PD subjects with motor fluctuations who were randomized to rasagiline or placebo and followed for 6 months. The primary outcome measures were UPDRS scores and "on-off" diaries.

TEMPO (Ira Shoulson PI, Teva Pharmaceutical Industries, Ltd. sponsor) was a study of 404 early PD patients not requiring dopaminergic treatment. They were randomized to 1 of 2 dosages of rasagiline or placebo and followed for 6 months. After 6 months the placebo group was started on the higher dosage of rasagiline and all groups were followed for a total of 12 months. Outcome measures include UPDRS scores and quality of life measures.

RAPID (Ira Shoulson PI, Teva Pharmaceutical Industries, Ltd. sponsor) was a study of 327 PD patients with motor fluctuations and advanced PD who were randomized to levodopa or etilevodopa. UPDRS scores and "on-off" diaries were the primary outcome measure.

PATCH (Ira Shoulson PI, Schwarz Pharma sponsor) was a study of 242 early, untreated PD patients who were randomized to 1 of 4 dosages of a topical patch delivered dopamine agonist or placebo and followed for 12 weeks. UPDRS scores were the primary outcome measure.

QE2 (Cliff Shults PI, Karl Kieburtz Co-PI, NINDS sponsor) was a study of 80 early, untreated PD patients randomized to 1 of 3 dosages of coenzyme Q_{10} or placebo and followed for a total of 16 months. UPDRS scores were the primary outcome measure.

ELLDOPA (Stanley Fahn PI, NINDS sponsor) was a study of 361 early, untreated PD patients who were randomized to 1 of 3 dosages of levodopa or placebo and followed for 9 months. The primary outcome measure was UPDRS scores.

TEST (Ira Shoulson PI, SIBIA Neurosciences, Inc. sponsor) was a study of 32 individuals who were randomized to several dosages of a nicotinic cholinergic agonist and evaluated using neuropsychological tests over a five week period.

DARE (Ira Shoulson PI, Astra Merck, Inc. sponsor) is a study of 40 individuals with PD and prominent dyskinesias. They were randomized to receive placebo or remacemide and were evaluated for the impact on dyskinesias over 4 weeks.

REAL (Ira Shoulson PI, Astra Merck, Inc. sponsor) was a study of 279 individuals with PD with advanced disease experiencing motor fluctuations. They were randomized to placebo or 1 of 4 dosages of remacemide, and tolerability and impact on "on-off" diaries was assessed over 12 weeks.

RAMP (Ira Shoulson PI, Astra Merck, Inc. sponsor) was a study of 200 PD subjects with early, untreated PD who were randomized to 1 of 3 dosages of remacemide or placebo for a total of 12 weeks, as an assessment of its tolerability. Outcome measures include UPDRS scores.

PRIME (Caroline Tanner PI, Cynthia Comella Co-PI, Pharmacia and Upjohn, Inc. sponsor) was a study of PD patients requiring levodopa treatment who were randomized to placebo or pramipexole. The study population consisted of ethnic minorities including Blacks, Hispanics and Asian Americans.

CALM-PD (Ira Shoulson PI, Pharmacia and Upjohn, Inc. sponsor) was a study of 301 subjects with PD who were just at the point of requiring treatment with dopaminergic agents. They were randomized to levodopa or pramipexole and followed for approximately 4 ½ years. Outcome measures include UPDRS scores and quality of life instruments. Health care utilization data are also available.

PSYCLOPS (Joseph Friedman PI, FDA sponsor) was a study of 60 individuals with Parkinson's disease who had visual hallucinations and psychosis. Individuals were randomized to clozapine or placebo and followed for 12 weeks.

SEESAW (Ira Shoulson PI, Orion-Farmos, Inc. sponsor) was a study of 205 PD patients with advanced PD who were experiencing wearing- off. They were randomized to entacapone or placebo and followed with UPDRS scores and "on-off" diaries for 6 months.

DOPASCAN (Ken Marek PI, Guilford Pharmaceuticals, Inc. sponsor) was a study of 96 individuals with 3 different conditions (PD, PSP, ET) and healthy subjects. The point of the investigation was to see if the imaging could differentiate parkinsonism (Parkinson's disease and PSP) from essential tremor and healthy subjects.

STEP-UP (Ira Shoulson PI, The Upjohn Company sponsor) is a study of 264 early PD subjects not receiving dopaminergic treatment. They were randomized to placebo or 1 of 4 dosages of pramipexole and followed for a total of 10 weeks. Outcome measures include UPDRS scores.

ROADS (Ira Shoulson PI, Hoffmann-LaRoche, Inc. sponsor) is a study of 321 early, untreated PD patients randomized to placebo or 1 of 4 doses of lazabemide, a monoamine oxidase inhibitor. They were followed for 1 year with serial UPDRS evaluations.

START-LE (Ira Shoulson PI, Hoffmann-LaRoche, Inc. sponsor) is a 12 week short term study of 137 subjects stably treated with levodopa. The tolerability of the monoamine oxidase inhibitor lazabemide was assessed.

START-UP (Ira Shoulson PI, Hoffmann-LaRoche, Inc. sponsor) is a 12 week short term assessment of a monoamine oxidase inhibitor (lazabemide) in 201 early, untreated PD subjects.

DATATOP (Ira Shoulson PI, NINDS sponsor) was supported by NINDS and enrolled 800 early, untreated PD subjects. They were followed for up to a total of about 8 years. During the period of follow up the original randomized treatment groups of deprenyl alone, tocopherol alone, both interventions, and double-placebo were modified at various stages. Deprenyl was converted to open-label approximately two years after initiation of the study and the tocopherol/placebo treatment assignment ended after approximately 3 years (DATE, Somerset sponsor). Later in the study subjects were again randomized to continue their deprenyl or taper off to placebo in a blinded fashion (BLIND-DATE, Somerset sponsor). Overall approximately 15,000 UPDRS observations are contained in the combined DATATOP database. Additional material includes cognitive testing and quality of life instruments. Associated biological specimens include serum, urine and CSF samples from the first 2 to 3 years of follow up, DNA on approximately two-thirds of the cohort and a videotape repository.