

(1) FERTILITY

Wurn BF, Wurn LJ, King CR, Heuer MA, Roscow AS, Hornberger K, Scharf ES. Treating fallopian tube occlusion with a manual pelvic physical therapy. *Alternative Therapies in Health and Medicine*. 2008 Jan-Feb;14(1):18–23.

Wurn BF, Wurn LJ, King CR, Heuer MA, Roscow AS, Scharf ES, Shuster JJ. Treating female infertility and improving IVF pregnancy rates with a manual physical therapy technique. *Medscape General Medicine*. 2004;6(2):51.

(2) MENOPAUSE AND OSTEOPOROSIS

Hormone Replacement Therapy

ClinTrials Research Inc./TheraTech, Inc. Comparison of Two Doses of an Estradiol Matrix Transdermal Delivery System (EMTDS) with Placebo Matrix Transdermal Delivery System I in the Treatment of Women with Postmenopausal Symptom, 1994.

Mead Johnson Laboratories: Evaluation of the Effect of the 0.5 mg Estrace Compared to Placebo on Biochemical Markers of Bone Resorption in Postmenopausal Women, 1994.

Novo Nordisk Pharmaceuticals, Inc.: Evaluation of Estrofem® 0.25, 0.5, 1.0, and 2.0 mg on Relief of Vasomotor and Other Symptoms of the Menopause, 1993.

Solvay Pharmaceuticals, Inc.: Study of Estrafied Estrogens Plus Methyltesterone (Estratest®) and Esterified Estrogens (Estratab® 1.25 mg) in Surgically Postmenopausal Women: symptoms, psychometric assessments, serum and saliva hormone levels, 1993.

Kabi Pharmacia: Comparison of a Continuous Low Dose of Estradiol Released from a Vaginal Ring vs. Conjugated Equine Estrogen in a Vaginal Cream in the Treatment of Postmenopausal Women with Signs and Symptoms of Urogenital Atrophy, 1992.

Solvay Pharmaceuticals, Inc.: Investigation of Three Doses of Esterified Estrogens (Estratab®) on Bone Mineral Density and Parameters of Bone Metabolism in Postmenopausal Women, 1992.

Solvay Pharmaceuticals, Inc.: Study of the Effects of Estratest H.S.®, Estratest®, and Premarin® in Surgically Menopausal Women, 1992.

Zeneca Pharmaceuticals Group: Comparison of 3.6 mg ZOLADEX therapy with or without hormone replacement therapy for the treatment of endometriosis, 1992.

Hormone Replacement Therapy—Protocols

Berlex Laboratories, Inc. (Protocol 96097). A Multicenter, Double-Blind, Randomized Comparison of Continuous Oral Estradiol-Drospirnone Combinations and Continuous Oral Estradiol: examining the effects on the endometrium, symptoms, and bleeding patterns in postmenopausal women.

ClinTrials Research, Inc. TheraTech, Inc. (Protocol E94001A). An Open-Label, Multicenter Extension of Protocol No. E94001 to Describe the Use of Two Doses of an Estradiol Matrix Transdermal Delivery System (EMTDS) in the Treatment of Women with Postmenopausal Symptoms.

Eli Lilly & Company (Protocol H3S-MC-GGHH). Comparison of Raloxifene HCl, Estrogen and Placebo on the Uterus in Healthy Postmenopausal Women.

Eli Lilly & Company (Protocol H3S-MC-GGHD). Comparison of Raloxifene HCL, Continuous Combined Hormone Replacement Therapy and Placebo in Early Postmenopausal Women: once a week Estradiol-Levonorgestrel combination transdermal system (TDS).

Ethical Pharmaceuticals (UK) Ltd. (Protocol EPCOUS02). A Clinical Evaluation of the Effects of Estradiol TD and Combi TD, Used Continuously, on Estradiol-Induced Endometrial Hyperplasia.

Novo Nordisk Pharmaceuticals, Inc. (Protocol VAG/PD/9/USA). A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Multicenter Study Comparing the Efficacy and safety of Vagifem 10 µg and 25 µg doses in Treatment of Estrogen Deficiency Derived Atrophic Vaginitis.

Novo Nordisk Pharmaceuticals, Inc. (Protocol KLIM/PD/7/USA). A Double-Blind, Randomized, Parallel Group, Multicenter, Dose Finding Study Comparing the Efficacy and Safety of 1 mg 17β-Estradiol in Combination with Low Doses of Norethindrone Acetate with that of 1 mg 17β-Estradiol Alone on the Endometrium in Postmenopausal Women.

Novo Nordisk Pharmaceuticals, Inc. (Protocol KLIM/USA/1/USA). Bleeding Profile with Continuous Combined Hormone Replacement Therapy: A randomized, double-blind, multicenter, comparative trial of 1 mg 17B-Estradiol in combination with 0.25 mg or 0.5 mg Norethindrone Acetate and Prempro®.

Ostex International, Inc. (Protocol OST-C2). A Study of the Use of Osteomark in the Quantitation of Cross-Linked N-telopeptides of a Type I Collagen as an Aid in Monitoring the Effect of Therapies Used for the Prevention and Management of Bone Loss in Postmenopausal Women.

Procter & Gamble Pharmaceuticals (Protocol 1996023). A Randomized, Double-Blind, Placebo-Controlled 24 Month, Dose Ranging, Multicenter Study Protocol Comparing

EMTDS to Placebo in the Prevention of Bone Loss in Hysterectomized Postmenopausal Women.

Procter & Gamble Pharmaceuticals/TheraTech (Protocol 1998049). A 12-week, Randomized, Parallel Group, Multicenter, Wear Study to Assess Skin Tolerance with a 40-Week Safety Extension Period Comparing Three Continuous Dose Regimens (0.1, 0.2, and 0.4 mg/day NETA Combined with 0.05 mg/day Estradiol) under Conditions of Routine Clinical Use.

Rhone-Poulace Rorer (Protocol RPR 106522-303). A Randomized, Double-Blind, Multicenter, Placebo-Controlled, Menopausal Symptom Study of Three Doses of RPR Estradiol Norethisterone Acetate (NETA) Patches in a Sequential Wear Hormone Replacement Therapy (HRT) Regimen.

R.W. Johnson PRI (Protocol ESTNRG-CHRT-102). A Multicenter, Randomized, Double-Blind, Parallel Group, Dose-Ranging Study to Evaluate the Safety of a Cyclophasic Hormone Replacement Therapy Regimen of Estradiol and Norgestimate and its Effects on Endometrial Histology, Vaginal Bleeding and Metabolic Parameters in Postmenopausal Women.

R.W. Johnson (Protocol ESTNRG-CHRT-104). A Multicenter, Double-Blind, Randomized Parallel Group, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Oral 17β -Estradiol for the Treatment of Vasomotor Symptoms and Genital Atrophy in Postmenopausal Women.

RW Johnson Pharmaceuticals Research Institute (Protocol ESTRNG-CHRT-106). A Multicenter, Randomized, Double-Blind Exploratory Study Investigating the Pharmacodynamic Profile of Two Different Hormone Replacement Therapy Regimens: conjugated estrogens plus Medroxyprogesterone Acetate vs. Micronized Estradiol plus cyclophasic addition of Norgestimate (Cyclophasic HRT) vs. Placebo in postmenopausal women.

Sterling Winthrop Pharmaceuticals (Protocol SR41319B-004). A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Established Post-Menopausal Osteoporosis.

The Upjohn Company (Protocol M5410/0336). Evaluation of Endometrial Histology and Bone Mineral Density (BMD) in Postmenopausal Women Receiving OGEN/PROVERA) Hormone Replacement Therapy (HRT).

Wyeth-Ayerst Research (Protocol 0802D1-324-US). A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel, Multicenter Study to Assess the Safety and Efficacy of 3 ½ Day Combinations of 17β -Estradiol/Norethindrone Acetate Transdermal Delivery Systems for Relief of Menopausal Vasomotor Symptoms and Reduction of Endometrial Hyperplasia.

Osteoporosis

Mead Johnson Laboratories: Evaluation of the Effect of the 0.5 mg Estrace Compared to Placebo on Biochemical Markers of Bone Resorption in Postmenopausal Women, 1994.

Solvay Pharmaceuticals, Inc.: Investigation of Three Doses of Esterifield Estrogens (Estratab®) on Bone Mineral Density and Parameters of Bone Metabolism in Postmenopausal Women, 1992.

Osteoporosis Protocols

Boehringer Mannheim Pharmaceuticals Corporation (Protocol MF4380). Double-Blind, Placebo-Controlled, Randomized, Multicenter Study on the Efficacy and Safety of Ibandronate (BM 21.0955) during Three Years Treatment in Patients with Postmenopausal Osteoporosis Using an Intermittent (every 3 months) I.V. Injection Regimen of 1 mg.

Eli Lilly & Company (Protocol H3S-MC-GGGK). Comparison of Raloxifene HCl and Placebo in the Treatment of Postmenopausal Women with Osteoporosis.

Eli Lilly & Company (Protocol H3S-MC-GGHF). Raloxifene HCl versus Placebo versus Hormone Replacement Therapy: Histomorphologic Effects in Bone Loss.

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/15/USA). A Double-Blind, Randomized Placebo-Controlled Trial of Three Doses of Levomeloxifene and Prempro® for the Prevention of Postmenopausal Osteoporosis.

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/16/USA). A Double Blind, Randomized, Multicenter, Placebo-Controlled Trial of 1.25 and 2.5 mg of Levormeloxifene for the Treatment of Postmenopausal Osteoporosis.

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/17/USA). A Double-Blind, Placebo-Controlled Trial to Study the Safety and Efficacy of 2.5, 10, and 40 mg of Levormeloxifene for the Prevention of Postmenopausal Bone Loss.

Organon, Inc. (Protocol 010-006). A Dose-Finding Efficacy & Safety Study of Tibolone (Org OD 14) for Prevention of Osteoporosis in Postmenopausal Women.

Ostex International, Inc. (Protocol OST-C2). A Study of the Use of Osteomark in the Quantitation of Cross-Linked N-telopeptides of a Type I Collagen as an Aid in Monitoring the Effect of Therapies Used for the Prevention and Management of Bone Loss in Postmenopausal Women.

Pfizer, Inc. (Protocol 174-106). A Randomized, Double-Blind, Placebo-Controlled Study of the Effects of Droloxifene 40 mg/d, 60 mg/d, and 80 mg/d on BMD in Osteopenic, Postmenopausal Women.

Pfizer, Inc. (Protocol 174-113). A Study of the Safety and Efficacy of Droloxifene for Preventing Bone Loss in Normal, Early Postmenopausal Women.

Pfizer, Inc. (Protocol A2181003-5045). A Study of the Safety and Efficacy of Lasofoxifene for the Prevention of Bone Loss and for Lipid Lowering in Postmenopausal Women at Risk for Osteoporosis.

Procter & Gamble Pharmaceuticals/G.H. Besselaar Associates (Protocol RPE 002494). A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Compare the Efficacy and Safety of Risedronate (NE-58095) plus Estrogen versus Estrogen Only in the Prevention of Bone Mineral Mass and No Vertebral Fractures.

Procter & Gamble Pharmaceuticals/G.H. Besselaar Associates (Protocol RVN008993). A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Determine the Efficacy and Safety of Risedronate (NE-58095) in the Treatment of Postmenopausal Women with Established Osteoporosis-Related Vertebral Deformities.

Procter & Gamble Pharmaceuticals / Quintiles Inc. (Protocol RHN009193). A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Determine the Efficacy and Safety of Risedronate in the Treatment of Osteoporosis in Elderly Women.

Procter & Gamble Pharmaceuticals (Protocol 1996023). A Randomized, Double-Blind, Placebo-Controlled 24 Month, Dose Ranging , Multicenter Study Protocol Comparing EMTDS to Placebo in the Prevention of Bone Loss in Hysterectomized Postmenopausal Women.

Roche Pharmaceuticals (Protocol MF4492). Double-Blind, Placebo-Controlled, Randomized, Multicenter Study on the Efficacy and Safety of Ibandronate During an Extended Two Year Partial Crossover Study of Patients Enrolled in MF4380 Using an Intermittent I.V. Injection Regimen of 0.5 mg and 1 mg Every 3 Months.

Sterling Winthrop Pharmaceuticals (Protocol SR 41319B-005). A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Post-Menopausal Women with Low Bone Mineral Mass and no Vertebral Fractures.

Sterling Winthrop Pharmaceuticals (Protocol SR41319B-004). A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Established Post-Menopausal Osteoporosis.

The Upjohn Company (Protocol M5410/0336). Evaluation of Endometrial Histology and Bone Mineral Density (BMD) in Postmenopausal Women Receiving Ogen/Provera) Hormone Replacement Therapy (HRT).

(3) GYNECOLOGICAL/UROLOGICAL CONDITIONS

Candidiasis

Bayer Corporation (Protocol S95-003). A Multicenter, Prospective, Randomized, Single-Blind, Parallel-Group Comparison of the Clotrimazole 1-Day (One 500 mg Vaginal Insert) and the Clotrimazole 3-Day Regimens (One 200 mg Vaginal Insert Daily for 3 Days) with Clotrimazole 7-Day Regimen (One 100 mg Vaginal Insert Daily for 7 Days) for the Treatment of Vulvovaginal Candidiasis.

Advance Care Products, Ortho Pharmaceutical Corporation (Protocol 94-007P). Phase III Study Comparing Miconazole Nitrate (4%) Vaginal Cream and Mixanazole Nitrate (2.8%) Vaginal Cream to Monistat® 7 (2%) Vaginal Cream in the Treatment of Vulvovaginal Candidiasis.

Endometriosis

IBAH / Searle Research and Development (Protocol N65-97-02-001). Clinical Protocol for a Dosing Optimization Study of Syneral® for Endometriosis: Safety and Efficacy of a Single 400µG Daily Dose for 6 Months and a Step-Down Dose from 200µG BID for 2 Months to 200µG Daily for 4 Months: a double-blind, placebo-controlled, randomized comparison to the currently recommended regimen of 200µG BID daily for 6 months, IND # 18,138.

Oral Contraceptives

Organon, Inc./Pharmaco LSR (Protocol 086-001). An Open Label, Multicenter, Non-Comparative Safety and Efficacy Study of the Desogestrel Containing Oral Contraceptive CTR 25.

Organon, Inc./Pharmaco LSR (Protocol 092-001). An Open-Label, Randomized, Parallel, Comparative, Multicenter, Safety and Efficacy Study of Triphasic Combination Oral Contraceptives, CTR 99 and CTR 77, versus Ortho-Novum 777.

Organon, Inc./Quintiles, Inc. (Protocol 069-001). An Open-Label Noncomparative Efficacy and Safety Study of Implanon, a one-Rod Contraceptive Implant Containing 3-Ketodesogestrel in Healthy Female Volunteers, with Subsets for Pharmacokinetic Measurements, Ophthalmological Assessments, Carbohydrate Metabolism, Lipid Metabolism and Endometrial Morphology.

Organon, Inc. (Protocol 147-001). A Randomized, Open-Label, Comparative, Multicenter Trial to Evaluate Contraceptive Efficacy, Cycle Control, Safety and Acceptability of a Monophasic COC Containing 200µg EE, Compared to a COC Containing 100µg Levonorgestrel and 20µg EE.

Ortho-McNeil Pharmaceutical (Protocol CAPSS022). A Comparison of Two Oral Contraceptives: Oral Tri-Cyclen® vs. Loestrin® Fe 1/20.

RW Johnson Pharmaceutical Research Institute (Protocol NRGEEP-CONT-004). An Open-Label Study to Evaluate Contraceptive Efficacy and Safety of the Transdermal Contraceptive System of 17-Deacetylnorgestimate and Ethinyl Estradiol with the Oral Contraceptive Triphasil.

Overactive Bladder and Urinary Incontinence

Eli Lilly & Company (Protocol H3S-MC-SAAL). Duloxetine versus Oxybutnin in Patients with Urge Incontinence: A Multiple-Dose Study for Efficacy and Safety.

Pharmacia & Upjohn Pharmaceuticals (Protocol 97 OATA 039). Dose Escalation Study with Tolterodine in Patients with Overactive Bladder: a single-blind study in patients with symptoms of overactive bladder including urinary urgency and frequency with or without urge incontinence.

Pharmacia & Upjohn Pharmaceuticals (Protocol 98-TOCR-007). Long-Term Safety and Efficacy of Tolterodine Prolonged Release Capsules: an open-label, uncontrolled, multinational study in patients with symptoms of overactive bladder.

Pharmacia & Upjohn Pharmaceuticals (Protocol 98-TOCR-007B). Long-Term Safety and Efficacy of Tolterodine Prolonged Release Capsules: an open-label, uncontrolled, multinational study in patients with symptoms of overactive bladder.

Urinary Tract Infection

Bayer (Protocol 100398). Prospective, Randomized, Double-Blind, Multicenter, Comparative Trial to Evaluate the Efficacy and Safety of Ciprofloxacin Once Daily Extended Release 500mg Tablets QD for 3 Days versus Conventional Ciprofloxacin 250mg Tablets BID for 3 Days in the Treatment of Patients with Uncomplicated Urinary Tract Infections.

(4) MISCELLANEOUS SUBJECTS. Other areas of investigation include the following:

Arthritis

GD Searle & Company (Protocol N49-98-02-102). Clinical Protocol for a Multicenter, Double-Blind, Parallel Group Study Comparing the Incidence of Clinically Significant Upper Gastrointestinal Adverse Events Associated with SC-58635 400 mg BID to that of Diclofenac 75 mg BID in Patients with Osteoarthritis or Rheumatoid Arthritis, IND # 48,395.

Merck Industries (Protocol 088-001). A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUB's During Chronic Treatment with MK-0966 or Naproxen in Patients with Rheumatoid Arthritis.

Chronic Bronchitis

Abbott Laboratories, Inc. (Protocol M97-766). Comparative Study of the Efficacy of Clarithromycin and Azithromycin for the Treatment of Patients with Acute Exacerbation of Chronic Bronchitis.

Community Acquired Pneumonia

Abbott Laboratories, Inc. (Protocol M98-939). Comparison of the Safety of Clarithromycin IR (250 mg) BID to Levofloxacin (500 mg OD) for the Treatment of Community-Acquired Pneumonia.

TAP Holdings (Protocol CEF-97-002) A Comparative Study on the Safety and Efficacy of Cefditoren Pivoxil and Cefpodoxime Proxetil in the Treatment of Community-Acquired Pneumonia.

Diabetes

Bristol-Myers Squibb/US Pharmaceuticals (Protocol CV 138-002). Comparative Outcomes Study of Metformin Intervention versus Conventional Approach: the cosmic approach study.

Insmed Pharmaceuticals (Protocol INS1-DM-28). A Randomized, Multicenter, Double-Blind, Parallel-Group Clinical Study to Compare the Effects of INS1 (D-Chiro-Inositol) versus Placebo as Initial Oral Therapy in Subjects with Type 2 Diabetes Mellitus who Fail to Achieve Adequate Glycemic Control with Diet and Exercise Alone.

Hypertension

ALLHAT National Trial on Hypertension Agents and Heart Disease. 5-year NIH trial.

GD Searle & Company (Protocol IE3-98-02-01). A Double-Blind, Placebo-Controlled, Randomized Study to Evaluate the Safety and Efficacy of Ranging Doses of Eplernone Relative to Placebo, Hydrochlorothiazide and Daily Dose Combinations of Eplernone and Hydrochlorothiazide for the Treatment of Mild to Moderate Hypertension.

Lipid Lowering

Pharmacia Corporation (Protocol NB4-00-02-009). Clinical Protocol for a Randomized, Double-blind, Placebo-controlled Study of SD-5613 as Monotherapy in Patients with Primary Hypercholesterolemia (Monotherapy) Assessment of Reducing Cholesterol [MONARCH]), IND #58,482.

Migraine

GlaxoWellcome. Imitrex Injection in the Treatment of Acute Migraine and Cluster Migraine.

GlaxoWellcome. Imitrex Injection vs. Imitrex Tablets in Chronic Severe Migraine.

Wyeth-Ayerst. Inderol LA in Chronic Severe Migraine: Inderol LA 160mg vs. Inderol 40mg TID vs. Calcium Channel Blocker.

Sinusitis

Abbott Laboratories (Protocol M00-225). Comparative Study of the Safety and Efficacy of ABT-773 150 mg QD vs. 150 mg BID for the Treatment of Acute Bacterial Sinusitis.

FUNDED RESEARCH SUPPORT

Miles, Inc. Clotrimazole 2% Vaginal Cream, 1993

Wyeth-Ayerst Laboratories. Trigonitis, 1992

SmithKline Beecham. Paxil, Carvedelol, Asthma, Arthritis, 1990-1991

3M/Bio: Pharm Estradiol Patch Study, 1990

Health & Sciences Research, Inc. Noven Patch Study, 1990

Organon, Inc. Desogestrel O.C. CTR-04 Study, 1990

Bartor. Estrapel and Effects of Estradiol Production Levels, 1989

Columbia Laboratories, Inc. Vaginal Moisturizing Gel Study, 1989

NIH (Co-Investigator with Dan Martin, Ph.D.). Walking and Bone Mass, 1988–1990

Ayerst. Estrogen, Exercise and Lipid Study, 1988–1990

Reid-Rowell. Estratab and Estratest and Effects on Lipids and Bone Mass, 1988–1990

Wallace Laboratories, 1987–1990

Felbamate Development Program for Lennox Gasteau Syndrome, Seizures
Organidin Reformulation Studies – cough /cold

Ciba-Geigy. Ophthalmologics, Antihypertensives, 1983-1984

Nautilus, Inc. Exercise Physiology and Osteoporosis, 1982-1990

Ayerst Laboratories, 1982–1986

- Altromid-S Protocols
- Inderal – Product Line Extension Hypertension
- Effexor – Antidepressant Study Program
- Lodine Development RA, OA Protocols
- PremPro Development Plan and Protocols
- Premarin Osteoporosis Program Development
- Prem Phase Development Plan and Protocols
- Various Oral Contraceptive Studies

Ayerst Laboratories. Premarin, GNRH, 1982

SmithKline Beecham, 1981–1984

- Diagnostic Bioequivalence Studies and Reformation
- Monoacid Injectable Antibiotic Development Protocols
- Paxil Antidepressant Studies UK and US
- Obsessive Compulsive Studies US
- Relafen Full Development Plan and All Protocols
- RA and OA; Pain
- Pharmacokinetic Studies
- Ridawra – OA and RA Study Program
- Topical Use Eczema Program
- Tagamet – Ulcer Peptic and Gastric Studies
- Various Ophthalmologics Topical – Antibiotics, Steroids

Schering Laboratories. Topical and Transdermal Delivery Systems, 1981-1982

Upjohn Laboratories. Depression, Hypertension, 1981-1983

Note: Additional sources of Funded Research Support include: Ayerst Laboratories, 1987; Abbott Laboratories, 1986; Florida Department of Health and Rehabilitative Services III, 1986; Lederle Laboratories, 1986; Nuclear Data, 1985-1986; Ayerst Laboratories, 1985; Wyeth Laboratories, 1985; Bruner Foundation, 1983–1985; FL Dept. of Health & Rehabilitative Services I, 1983; FL Dept. of Health & Rehabilitative Services II, 1983–1984; and Schering Laboratories, 1983–1984.