

CURRICULUM VITAE: DANIEL J. WALLACE, M.D., F.A.C.P., M.A.C.R.

Up to date as of January 1, 2019

Personal:

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Education:

University of Southern California, 2/67-6/70, BA Medicine, 1971.
University of Southern California, 9/70-6/74, M.D, 1974.

Postgraduate Training:

7/74-6/75 Medical Intern, Rhode Island (Brown University) Hospital, Providence, RI.
7/75-6/77 Medical Resident, Cedars-Sinai Medical Center, Los Angeles, CA.
7/77-6/79 Rheumatology Fellow, UCLA School of Medicine, Los Angeles, CA.

Medical Boards and Licensure:

Diplomate, National Board of Medical Examiners, 1975.
Board Certified, American Board of Internal Medicine, 1978.
Board Certified, Rheumatology subspecialty, 1982. California License: #G-30533.

Present Appointments:

Medical Director, Wallace Rheumatic Study Center
Attune Health Affiliate, Beverly Hills, CA 90211
Attending Physician, Cedars-Sinai Medical Center, Los Angeles, 1979-
Clinical Professor of Medicine, David Geffen School of Medicine at UCLA, 1995-
Professor of Medicine, Cedars-Sinai Medical Center, 2012-
Expert Reviewer, Medical Board of California, 2007-
Associate Director, Rheumatology Fellowship Program, Cedars-Sinai Medical Center, 2010-
Board of Governors, Cedars-Sinai Medical Center, 2016-
Member, Medical Policy Committee, United Rheumatology, 2017-

Honorary Appointments:

Fellow, American College of Physicians (FACP)
Fellow, American College of Rheumatology (FACR) 1979-2015
Master, American College of Rheumatology, 2015-
Member, Royal College of Physicians (London)
Organizing Committee: Lupus 2014, Quebec, Quebec, Canada

Hospital Appointments:

Cedars Sinai: **Clinical Chief of Rheumatology, 1991-1996**
Chairman, Medical Peer Review 1985-1987, Member 1982-1989
Intern Selection Committee, 1979-1993
Medical Advisory Committee, 1985-1988, 1991-1996
Performance Improvement Committee, 1991-1996
Hospital Peer Review Committee, 1986-1989, 1992-1994
Division of Rheumatology Reappointment/Peer Review, 1988-present
Pharmacy gamma globulin committee, 2002-present
Chairman of Department of Medicine Search Committee 2011-2012
Clinical Academic Promotions and Appointments Council 2011-2014
Division of Rheumatology Executive Committee 2011-

Chief Rheumatology Consultant, City of Hope Medical Center, Duarte, CA 1980-1988

Attending Physician, UCLA Center for the Health Sciences, 1981-

Prior Academic Appointments:

Associate Clinical Professor, UCLA School of Medicine 1988-1995
Assistant Clinical Professor, UCLA School of Medicine, 1981-1988
Assistant Clinical Professor, USC School of Medicine 1979-1981

Books

1. Wallace, DJ and Dubois EL, eds., Dubois' *Lupus Erythematosus, 3rd Edition*, Lea and Febiger, Philadelphia, PA, 1987, 775 pp
2. Wallace, DJ and Hahn, BH, eds, Dubois' *Lupus Erythematosus, 4th Edition*, Lea and Febiger, Philadelphia, PA, 1993, 953 pp
3. Wallace DJ, *The Lupus Book*, Oxford University Press, NY/London, 1995, 258 pp
4. Wallace DJ, Hahn BH, Eds., Dubois' *Lupus Erythematosus, 5th Edition*, Williams and Wilkins, Baltimore, MD, 1997, 1289 pp
5. Wallace DJ, Wallace JB, *Making sense of fibromyalgia*, Oxford University Press, NY/London, 1999, 242pp
6. Wallace DJ, *The Lupus Book, New and Revised*, Oxford University Press, NY/ London, 2000, 271 pp
7. Lane NE, Wallace DJ, *All About Osteoarthritis*, Oxford University Press, NY/London, 2001, 258 pp.
8. Wallace DJ, Hahn BH, Eds, Dubois' *Lupus Erythematosus, 6th Edition*, Lippincott Williams & Wilkins, Philadelphia, PA, 2002, 1348 pp
9. Wallace DJ, Wallace JB, *All About Fibromyalgia*, Oxford University Press, NY/London, 2002, 258 pp
10. Wallace DJ, Wallace JB, *Fibromyalgia: An essential guide for patients and their families*, Oxford University Press, NY/London, 2003, 196 pp.
11. Wallace DJ, Editor, *The New Sjogren's Syndrome Handbook*, Oxford University Press, NY/London, Revised and Expanded 3rd Edition, 2005, 265 pp.
12. Wallace DJ, Clauw DJ, *Fibromyalgia and other central pain syndromes*, Lippincott Williams & Wilkins, Philadelphia, PA, 421 pages, 2005. 10.
13. Wallace DJ, *The Lupus Book: A Guide for Patients and their Families*, Oxford U Press, NY/London, 2005, 291 pp.
14. Wallace DJ, Hahn BH Eds, Dubois' *Lupus Erythematosus, 7th Edition*, Lippincott Williams & Wilkins, 2007, Philadelphia, PA, 1441 pp.
15. Wallace DJ, *Lupus: The Essential Clinician's Guide*, Oxford American Rheumatology Library, Oxford University Press, New York, 2008.
16. Clauw DJ, Wallace DJ, *Fibromyalgia: The Essential Clinician's Guide*, Oxford American Rheumatology Library, Oxford University Press, New York, 2009.
17. Wallace DJ, Editor, *The Sjogren's Book: Sjogren Syndrome Foundation*, Fourth Edition, Oxford University Press, New York 2012, 395 pages.
18. *Rheumatoid Arthritis*, Michael Weisman, Oxford American Rheumatology Library, Daniel J Wallace, Series Editor, 90 pages, 2011.
19. Wallace DJ, Hahn BH, *Dubois' Lupus Erythematosus and Related Syndromes, 8th edition*, Elsevier Saunders, Philadelphia, PA, 694 pages, 2013
20. Wallace DJ, *The Lupus Book: A Guide for patients and their families*, Oxford U Press, NY/Oxford, 2013.
21. Wallace DJ, *Lupus: The Essential Clinician's Guide*, Oxford American Rheumatology Library, Oxford U Press, Oxford/New York, 2014. 115 pp.
22. Wallace DJ, Wallace JB, *Making Sense of Fibromyalgia*, Oxford U Press, NY/Oxford, 2nd Edition, 2014, 257 pp.
23. Wallace DJ, Hahn BH, *Dubois' Lupus Erythematosus and Related Syundromes, 9th edition*, Elsevier, Philadelphia, PA 2018 (in press), DJ Wallace and BH Hahn, Editors, Dubois Lupus Erythematosus and Related Syndromes, 9th edition, Elsevier, 2019, 800 pp, Edinburgh
24. Wallace DJ, Venuturupalli RS, Editors, *Rheum Dis Clin NA 2018, Best Practices and Challenges to the Practice of Rheumatologists*, Elsevier, 2019, Philadelphia, PA

Book Chapters/Supplements

1. Plasma-lymphocytapheresis for the treatment of rheumatoid arthritis, D. Goldfinger, D. Wallace, J. Klinenberg, in *Plasma Exchange Therapy*, Ed. by H. Borberg, R Reuther, pp. 215-219, GeorgThiemeVerlag, Stuttgart, 1981.
2. The current status of therapeutic apheresis in the management of rheumatoid arthritis, DJ Wallace, D. Goldfinger, J. Klinenberg, in *Therapeutic Apheresis and Plasma Perfusion*, Ed. by J Tyndall, AR Liss, New York, pp. 27-32, 1982. (Also published as Prog. Clin. Biol. Res. 106:27-32 1982).
3. A controlled study on the use of plasmapheresis in steroid/immunosuppressive resistant systemic lupus erythematosus with nephrotic syndrome, DJ Wallace, D Goldfinger, S. Nichols, D Goodman, M Fichman, M Stewart, JR Klinenberg, in *Proceedings of the First International Congress of the World Apheresis Association*, Ed. by T Uda,

- Y Shlokawa, N Inoue, ISAO Press, pp. 91-102, 1987.
4. New and experimental therapeutic modalities, JR Klinenberg and DJ Wallace, in *Diagnosis and Management of Rheumatic Diseases*, W. Katz, ed, Lippincott, Philadelphia, pp 855-858, 1988.
 5. Wallace D, The Treatment of Mild Lupus, in *Proceedings of the 2nd Intl Conference on S.L.E., Professional Postgraduate Services*, Singapore, 1989, pp. 126-129.
 6. Wallace DJ, Peter JB, Bowman RL, Wormsley SB, Silverman S, Fibromyalgia, cytokines, fatigue syndromes, and immune regulation, in *Advances in Pain Research and Therapy: Myofascial Pain and Fibromyalgia, Volume 17*, JR Friction and EA Awad, Eds, Raven Press, NY, 1990, pp. 277-287.
 7. Wallace D, Metzger AL, The antiphospholipid syndrome, in *A Decade of Lupus*, H Aladjem editor, Lupus Foundation of America, 1991, Rockville, MD, pp. 126-127.
 8. Wallace DJ, Does stress or trauma cause aggravate rheumatic disease?, in *Bailliere's Clinical Rheumatology, Exercise and Rheumatic Disease*, 8: 149-159, 1994. Richard Panush and Nancy Lane editors, Bailliere Tindall, London.
 9. Wallace DJ, Antimalarial agents and lupus. Rheumatic Disease Clinics, in *Systemic Lupus Erythematosus*, WJ McCune editor, 20: 243-263, 1994, WB Saunders, Philadelphia, PA.
 10. Wallace DJ, Metzger AL, Ashman RF, Rheumatic diseases, in *Manual of Allergy and Immunology, 3rd edition*, G Lawlor, T Fischer, D Adelman, eds, Little, Brown & Company, 1995, pp 303-352.
 11. Silverman S, Gluck O, Silver D, Tesser J, Wallace D, Neumann K, Metzger A, Morris R, The prevalence of autoantibodies in symptomatic and asymptomatic patients with breast implants and patients with fibromyalgia, in *Immunology of Silicones*, M Potter and NR Rose, Eds, Springer-Verlag Berlin, Heidelberg, Germany, pp 317-322, 1996. (Also published as *Curr Top Microbiol Immunol* 1996; 210:317-322.)
 12. Wallace D, Metzger AL, Systemic lupus Erythematosus: Clinical aspects and treatment, in Koopman WJ, editor, *Arthritis and Allied Conditions: A Textbook of Rheumatology, 13th Edition*, Williams and Wilkins, Baltimore, MD, 1997, pp 1319-1345.
 13. Wallace D, Autoimmune Connective Tissue Disorders, Rakei RE, *Conn's Current Therapy 2000*, WB Saunders, Philadelphia, PA, pp 774-778.
 14. Wallace DJ, Severe lupus, in *Rheumatology (3rd Ed)*, MC Hochberg, AJ Silman, JS Smolen, ME Weinblatt, MH Weisman, Mosby, Edinburgh, 2003, pp. 1419-1426.
 15. Shinada S, Wallace DJ, Laboratory features of cutaneous lupus, *Cutaneous lupus erythematosus*, Springer, Berlin, 2004, p.p. 311-322.
 16. Wallace DJ, Fibromyalgia and the neurobiology of sleep, in *Sleep and Psychosomatic Medicine*, SR Pandi-Perumal, RR Ruoti, M Kramer, Eds, 2007; Informa Healthcare, Abington, United Kingdom, pp. 249-259.
 17. Wallace DJ, Systemic lupus erythematosus, *Encyclopedia of Stress*, 2nd edition, G Fink, editor, Elsevier, 2007, Oxford UK, v 3 pp 708-712.
 18. Hallegua DS, Wallace DJ, Sleep and fibromyalgia in the elderly, in *Principles and Practice of Geriatric Sleep Medicine*, SR Pandi-Perumal, JM Monti and AA Monjan, Eds, Cambridge University Press 2009, pp 160-166.
 19. Wallace DJ, Management of nonrenal systemic lupus erythematosus 2, in *Targeted Treatment of the Rheumatic Diseases*, M Weisman et al Eds, Saunders Elsevier, Philadelphia, PA, 2009, pp 91-107.
 20. Goldenberg DM, Wallace DJ, Epratuzumab in SLE, In: *Immunotherapeutic agents for SLE*. Shoenfeld Y, Meroni PL, Cervera R (Eds). Future Medicine Ltd, London, UK, 56-68 (2012).
 21. Editor of Up to Date sections since 2011 for: a) Antimalarial drugs in the treatment of rheumatic diseases, b) Diagnosis and differential diagnosis of systemic lupus erythematosus in adults, c) Musculoskeletal manifestations of systemic lupus erythematosus, d) Overview of therapy of the therapy and prognosis of systemic lupus erythematosus in adults, e) Patient education: Systemic lupus erythematosus (Beyond the Basics), Lippincott
 22. Wallace DJ, Management of nonrenal and non-central nervous system lupus, in *Rheumatology (5th edition)*, MC Hochberg, AJ Silman, JS Smolen, ME Weinblatt, MH Weisman Eds, Saunders Elsevier, Philadelphia, PA 2014, Chapter 134 pp 1099-1106.
 23. Wallace DJ, Fibromyalgia and the neurobiology of sleep, in *Sleep and Psychosomatic Medicine*, SR Pandi-Perumal, Narasimhan, Kramer M, Eds. 2016, pp 127-136, 2nd edition, CRC Press, Boca Raton, FL
 24. Wallace DJ, Editor, Special Issue: Biologic Therapies, *Lupus* 2016; volume 25, number 10
 25. Wallace DJ, Weisman MH, Clinical features of systemic lupus erythematosus, in *Rheumatology (6th edition)*, MC Hochberg, E Gravallese, A Silman, J Smolen, ME Weinblatt, MH Weisman, Eds, Elsevier, Philadelphia, PA, 2018, Chapter 135, pages 35.1-35.12.
 26. Wallace DJ, Systemic and Biologic Agents for Lupus Erythematosus, Springer, Cham Switzerland, 2018, in *Biologic and Systemic Agents in Dermatology*, Paul Yamauchi Ed, 2018, pp 377-390
 27. Lee CH, Wallace DJ, Clinical Trials in Rheumatology, *Rheum Dis Clin N Am* 2019; 45:79-85, in *Rheum Dis Clin NA*, 2018, Best Practices and Challenges to the Practice of Rheumatologists
 28. Wallace DJ, Venuturupallil RS, Preface: Best Practices and Challenges to the Practice of Rheumatologists,

2019; 45: xv-xvi, in in Rheum Dis Clin NA, 2018, Best Practices and Challenges to the Practice of Rheumatologists

Organizations and Positions Held:

Lupus Foundation of America

Co-chairman, 1999-2000

Member, Board of Directors 1991-1998, Vice President 1999-2000

National Medical Advisory Board, 1988-

Los Angeles Chapter Medical Advisory Board, Co-Chair 1989-1999

Member, Los Angeles County Medical Association

Member, California Medical Association

Member, American Medical Association

Member, Southern California Rheumatism Society

Member, Arthritis Foundation Pacific Region

LA. Metro Committee Chairman, 1989-1994

Community Services Committee, 1989-1994

Medical and Scientific Committee, 1989-1994

Institutional Grants Committee, 1989-1994

Fibromyalgia Subcommittee, 1988-; Chairman 1990-1995

Representative, National House of Delegates, 1987, 1990

Board of Directors, Southern California, 1994-2006

Member, American College of Rheumatology

Committee on Rheumatologic Practice, 1982-1985

Lupus Council, 1986-; Chairman 1990-1991

Nominations Committee 1991-1994

Research & Education Foundation Board of Directors, 1993-1999; Chairman 1995-1999

Nominating Committee, 2005-2007

Lupus Abstract Selection Committee 2010-2015

Research and Education Foundation, National Advisory Council Meeting, 2011-

The American Lupus Society (merged with Lupus Foundation of America, 1996)

National Medical Advisory Board, 1988-1996

Los Angeles Chapter Medical Advisory Board, 1980-1996

Los Angeles Chapter Chief Medical Advisor, San Fernando Valley Medical Advisory Board

Member, American Society for Apheresis

Medical Executive Committee, 1987-1989

Editor, *ASFA Newsletter*, 1987-1989

United Scleroderma Foundation Board of Directors, 1990-1997

Scleroderma Foundation, Southern California, Board of Directors, 2001-2004

American Fibromyalgia Syndrome Association, Medical Advisory Board, 1994-

Board of Directors, Lupus Research Institute, 2000- 2015

Founder, Lupus LA 2000-

Co-Chairman, Industrial Relations Council 2012-

Sjogren's Syndrome Foundation Medical Advisory Board, 1997-

Medical Advisory Board, Maryland Lupus Foundation, 2001-2004

Examination writer, American Board of Internal Medicine, for Internal Medicine Boards, 1994, 1995

Member, SLICC (Systemic Lupus International Coordinating Committee), 2003-

NIH Lupus Biomarkers Committee, 2004-2010

Member, Lupus Clinical Trials Consortium (LCTC), 2005-2010

Scientific Advisory Board for lupus, 23andme, 2015-

NYU Judith and Stewart Colton Center for Autoimmunity, NYU Langone Medical Center, External Advisory Committee, 2014-

Lupus Research Alliance, Co-chairman, Lupus Industry Council 2016-

Executive Board, Lupus Clinical Investigative Network, 2016-

Laboratory Experience:

Therapeutic apheresis project, Cedars-Sinai Medical Center, 1977-1997

Cedars-Sinai Lupus Research Laboratory 1990-

Summer research fellow, Cedars-Sinai Medical Center, 1968-1970, under Dr. Leon Morgenstern,

Chairman, Department of Surgery, dealing with wound healing of intestinal anastomoses and synthesizing trypsin inhibitor.

USC Cancer Virology Laboratory, Dr. Murray Gardner and J. Earle Officer, PhD, 1972-1974, retroviruses and aging.

Publication Review Experience:

Editorial Board, *Journal of Clinical Apheresis*, 1982 -2004
Editorial Board, *Lupus*, 1997-
Editorial Board, *Bulletin on the Rheumatic Diseases*, 1998-2004
Editorial Board, *Arthritis & Rheumatism*, 1998- 2003
Editorial Board, *Journal of Musculoskeletal Pain*, 1999-
Editorial Board, *Journal of Rheumatology*, 1999-
Editorial Board, *Journal of Clinical Rheumatology*, 2003-
Editorial Board, *Future Rheumatology*, 2006-2016
Editor, *Current Opinion in Rheumatology*, Lupus issues, 1994-2000
Editor-in-Chief, *Current Rheumatology Reviews*, 2005-2008
Reviewer for over 50 medical journals

Honors

Globus Award, Best Medical Paper, 1984-5, *Mt. Sinai J Medicine*
Humanitarian Award, Lupus Foundation of America, 1989 and 1991
Best Doctors in the United States, Town and Country Magazine, October, 1989
The American Lupus Society, Lupus Hall of Fame, 1989
"The Best Doctors in America," Woodward/White, Aiken, SC, 1994
Best Doctors in Los Angeles, *Los Angeles Magazine*, 1996
Jane Wyman Humanitarian Award, Arthritis Foundation, 1996
Expert Consultant, Medical Board of California, 1995-
Lupus Foundation of America, Outstanding Service Award, 1997
"Spirit of Hope" Award, Southern California Scleroderma Foundation, 2001
Achievement Award, SLE Foundation, 2002
James R Klinenberg Achievement Award, Arthritis Foundation Southern California Chapter, 2004
Founder's Award, Lupus LA, SLE Foundation, 2008
Top Doctor, US News and World Report, 2011-
Medical Achievement Award, SLE Foundation 2011
Sjogren's Syndrome Foundation, Healthcare Professional Leadership Award, 2012
Lupus Foundation of Northern California, Outstanding Commitment to Treatment and Research, 2016
Los Angeles County Medical Association, Innovation Award for Community Service, 2017
Jane Wyman Humanitarian Award, Arthritis Foundation, 2018

Research Grants:

BSRG Cedars-Sinai Research Grant, \$10,000, 1978-1979,
Apheresis in rheumatoid arthritis
Haemonetics Research Institute Grant, \$25,000, 1980-1981,
Double-blind controlled trial of apheresis in rheumatoid arthritis
Kroc Foundation Grant, \$59,000, 1981-1982,
Apheresis in systemic lupus erythematosus
Haemonetics Research Institute Grant, \$25,000, 1982,
The immunology of apheresis
Parker Foundation Grant, \$76,250, 1983-1985,
Selective immunoadsorption in rheumatoid arthritis
Winthrop Pharmaceuticals Grant, \$5,000, 1989-199,
The role of hydroxychloroquine on lipids
The American Lupus Society Grant, \$28,000, 1990-1992,
An index of lupus literature
Winthrop Pharmaceuticals Grant \$7,500, 1991-1993,
Cytokines and their influence on hydroxychloroquine
Co-Investigator with Dr. Mariana Linker-Israeli, 3 year NIH grant for \$350,000
"Interleukin-6 genetic polymorphisms", 1994-1996
Co-Investigator with Dr. Mariana Linker-Israeli, NIH grant for \$442,670,
"Abnormal IL-6 Production in SLE," Agency Award #2RoIAR4252-04, 1997-1999
American Fibromyalgia Syndrome Association, \$24,600, 1998-1999,
The role of the Th-1/Th-2 axis in fibromyalgia

Food and Drug Administration, RF 412-3324A, \$24,000, 2000-2002

Comparison of IV cyclophosphamide to mycophenolate mofetil for induction therapy of active nephritis in systemic lupus erythematosus. Co-investigator with M Weisman for Cedars effort Class III-IV
Co-investigator with Dr. Michelle Petri, NIH Grant, Brain Connections: Cognitive function in SLE, National Institute of Arthritis, Musculoskeletal and Skin disorders, 2003-, Grant number: R01AR4912501, 2004-2008
AROSE: Revising ACR diagnostic/classification criteria for lupus, Lupus Foundation of America, NIH-NIAMS ARO051871-013, 2004-2009

The role of mycophenolate mofetil in patients with extra-renal lupus, Aspreva, \$62,500, 2006-

A study to investigate pro-inflammatory HDL cholesterol as an indication of risk for atherosclerosis in subjects with systemic lupus erythematosus, Alliance for Lupus Research, \$72,500, 2006-2008

Co-investigator, Rituxan in the treatment of refractory adult and juvenile dermatomyositis (DM) and adult polymyositis (NIH Grant # N01-AR-4-2273), 2007-2010

Co-investigator, The use of abatacept in lupus nephritis (NIH Grant # N01A115416), 2008-2014

HHSN268200700036C Langford (PI) 09/13/10 – 08/14/12

Concurrent Pilot Studies in Giant Cell Arteritis and Takayasu Arteritis to Examine the Safety, Efficacy, and Immunologic Effects of Abatacept (CTLA4-IG) in large Vessel Vasculitides

The purpose of this study is to determine the effectiveness and safety of the medication abatacept in giant cell arteritis or Takayasu's arteritis.

Role: Co-Investigator

Canadian Arthritis Society Clarke/Bernatsky (PI) 05/05/09 – 12/31/11

Lymphoma Risk in SLE: A Consequence of Immune Suppression or Stimulation?

The purpose of this research is to help identify SLE patients at highest risk for lymphoma and provide guidance regarding the appropriate use of ISDs in both inducing and maintaining remission in SLE.

Role: Co-Investigator

Wallace (PI) Improving the Recognition, Diagnosis, and Referral Patterns of Patients with Systemic Lupus Erythematosus Through Enhanced Care Coordination and Practice Efficiencies – A QI/PI CME Demonstration Project for the Cedars-Sinai Medical Group, France Foundation, 2012- , \$150,000

BASJ02-A randomized, double-blind, placebo controlled trial of Baminercept, a omphotoxin-B receptor fusion, protein, for the treatment of primary Sjogren's syndrome, 2012-2016, Autoimmune Centers of Excellence

Subject: Introduction and Contact Information for the Protocol, "A Phase Ib Study of Milatuzumab Administered Subcutaneously in Patients with Active Systemic Lupus Erythematosus (SLE)," Submitted by Daniel Wallace MD, Cedars-Sinai Medical Center, Los Angeles, California in Support of Proposal, "CD74 Immunotherapy of Systemic Lupus Erythematosus," William Wegener MD, Immunomedics, Incorporated, Morris Plains, New Jersey, Proposal Log Number PR121764, Award Number W81XWH-13-1-0392, HRPO Log Number A-17786, 2014-

NIH R34A114453; Planning grant for 'Mesenchymal Stem Cell Therapy for Active Systemic Lupus Erythematosus' (7/15/14-6/30-15), Co investigator

5P50AR060804-03; Oklahoma Sjogren's Syndrome Center of Research Translation (7/1/13-6/30/15), Co-Investigator

U34 AR067392

Olsen & Karp (MPIs)

02/01/15-01/31/17

NIH/NIAAMS

Hydroxychloroquine Treatment for Prevention of Systemic Lupus Erythematosus

Planning grant for a multicenter, placebo-controlled trial of hydroxychloroquine in incomplete lupus patients to determine whether this can ameliorate, delay or prevent progression to SLE.

Role: Co-investigator

LR170141 (Department of Defense); Subject: "Inflammation and Metabolic Reprogramming of Lupus Monocytes – Mechanism of the Pathobiology of Lupus Cardiovascular Disease"

PI: Caroline Jefferies (2018 -

Role: Co-Investigator

Past Drug Study Collaborative Protocols:

Eli Lilly, Benoxaprofen, 1977-1979 in RA

Syntex, Naproxen, 1980-1982 in RA

CIBA-Geigy, Diclofenac, 1985-1987 in RA

Winthrop, Hydroxychloroquine-methotrexate, 1988-1992 in RA

Rorer, Calcitonin in Fibromyalgia, 1989

Sandoz, Sandostatin in Fibromyalgia, 1990-1991

Smith-Kline, Namebutone for Osteoarthritis, 1991-1992

Genelabs, Dehydroepiandrosterone (DHEA) for Lupus, 1994-1997, an open label and double blind trial

La Jolla Pharmaceuticals, LJP 394 for Lupus Nephritis, 1996-1999, Double-blind trial

Immunex, Double-blind trial of TNF-alpha (Enbrel) for Rheumatoid Arthritis, 1997-1999

Boehringer-Ingelheim, Meloxicam for Rheumatoid Arthritis, 1998-1999

Boehringer-Ingelheim, Meloxicam for Osteoarthritis, 1998-1999

Merck, MK-0966 for Rheumatoid Arthritis, 1998

Immunex, Open-label trial of TNF-alpha (Enbrel) for Rheumatoid Arthritis, 1997-

Biogen, Anti-CD40L therapy for lupus nephritis, 1998-1999

Smith Kline, SB 217969/Clenolixib for Rheumatoid Arthritis, 1998-1999

La Jolla Pharmaceuticals/Abbott, LJP 394 for Lupus nephritis, open label #90-11, 1998-2000

Merck, MK-0966 for osteoarthritis, 1998-1999

Smith Kline, SB 217969/Clenolixib (Open Label), for rheumatoid arthritis 1998-1999

Roche, Randomized, double-blind trial of Ro32-3555 (Trocade) for rheumatoid arthritis, 1998-2000

Amgen, A randomized, placebo controlled double-blind, multicenter, dose-finding study to evaluate the safety and efficacy of weekly administration of PEGylated recombinant methionyl human soluble tumor necrosis factor receptor Type I (PEGsTNF-RI) in patients with rheumatoid arthritis, 1999-2000

Merck, An active comparator and placebo controlled, parallel group, double-blind 52 week study to assess safety and efficacy of MK-0966 in rheumatoid arthritis patients, 1999-2000

Merck, Randomized, double-blind multicenter study to evaluate tolerability and effectiveness of rofecoxib (MK-0966) 25 mg/d vs naproxen 500 mg bid in patients with osteoarthritis, 1999-2000

Zeneca, Randomized, double blind placebo controlled, parallel group multicenter trial to assess the analgesic efficacy and tolerability of treatment with multiple doses of 1600 mg ZD6416 bid compared with treatment with placebo in patients with osteoarthritis of the hip or knee, 1999-1999

Biogen C99-1021, An open label, multiple dose study to evaluate the efficacy, safety and pharmacokinetics of BG 9588 (anti CD40 antibody) in subjects with proliferative lupus glomerulonephritis, 1999-2001

Anergen, A phase I double blind, randomized placebo controlled, dose escalation study to evaluate the safety, tolerability and biological activity of a 2 week induction course and 1 maintenance cycle of AG 4263 in subjects with rheumatoid arthritis, 1999-1999

IDEC, Phase II randomized, double blind, placebo-controlled, multiple center, multiple dose, dose finding safety, tolerance and efficacy study of IDEC-131 in patients with active SLE, 1999-2000

Centocor, An open-label trial of anti-TNF chimeric monoclonal antibody Infliximab in patients with active rheumatoid arthritis, 1999-2000

Merck, A randomized, placebo-controlled, parallel group, double-blind study to evaluate the safety and efficacy of rofecoxib 25 mg and celecoxib 200 mg in patients with osteoarthritis of the knee or hip, 2000

Cypress, A post approval, market preference, unblinded general experience study to gather additional information about the Prosrba column in general rheumatology practice settings, 1999-2000

Searle, Clinical protocol to evaluate the long term safety of valdecoxib in treating the signs and symptoms of rheumatoid arthritis, 1999-2001

Searle, Clinical protocol of a multicenter, double-blind, placebo-controlled randomized, comparison study of the efficacy and safety of 3 valdecoxib doses and naproxen in treating the symptoms and signs of rheumatoid arthritis, 1999-2001

Knoll, A multicenter randomized placebo-controlled Phase II study of the human anti-TNF D2E7 administered as subcutaneous injections in rheumatoid arthritis patients treated with methotrexate, 1999-2001

Knoll, A multicenter Phase II study of the human anti-TNF antibody D2E7 administered as subcutaneous injections in rheumatoid arthritis patients treated with methotrexate, 2000-2001

Amgen, A double-blind extension study to provide treatment with PEGylated recombinant human methionyl soluble tumor necrosis factor Type I (PEG sTNF-R1) to subjects completing trials TNF 980246 and TNF 990136, 2000

Fujisawa, An open-label, long-term study to evaluate the safety of Prograf (tacrolimus) for the treatment of rheumatoid arthritis, 2000-2002

Fujisawa, a randomized double-blind placebo controlled study to assess the efficacy and safety of prograf (tacrolimus) in the treatment of rheumatoid arthritis in patients who have failed one or more disease modifying antirheumatic drugs, 2000-2002

Knoll DE031: A multicenter randomized double-blind placebo-controlled study of the safety of human anti-TNF monoclonal antibody D2E7 in patients with active rheumatoid arthritis, 2000-2008

Knoll, Study of New Onset Rheumatoid Arthritis (SONORA), 2000-2006

Knoll DE013, A prospective multicenter randomized double-blind active comparator-controlled parallel-groups study comparing the fully human monoclonal antibody TNF alpha antibody D2E7 every second week with methotrexate given weekly and the combination of D2E7 and methotrexate administered over 2 years in patients with early rheumatoid arthritis, 2000-2008

La Jolla Pharmaceuticals, LJP 394-90-09, A randomized, double-blind, placebo-controlled, multicenter safety and efficacy trial of LJP 394 in systemic lupus erythematosus (SLE) patients with a history of renal disease, 2000-2002

Centocor, MEDIII Pso-A-1, A multicenter placebo, controlled, double blind, randomized study of anti-TNF chimeric monoclonal antibody (cA2, infliximab) in patients with active psoriatic arthritis, 2000-2002

Bristol-Myers Squibb, IM 101-101, A multicenter, randomized, double-blind, placebo controlled study to evaluate the safety and efficacy of intravenous infusions of BMS-188667 given monthly in combination with sub-cutaneous injections of etanercept given twice weekly to subjects with active rheumatoid arthritis, 2001-2008

Amgen, 2000223, A multicenter double-blind study to evaluate the safety and efficacy of anakinra (r0metHul IL-ra) and etanercept in subjects with rheumatoid arthritis using methotrexate, 2001-

Allergan, 192371-011-01, A multicenter, double masked, randomized, vehicle controlled parallel group study of the safety and efficacy of cyclosporin ophthalmic emulsion used twice daily for 6 months in patients with moderate to severe keratoconjunctivitis, 2001-2002

Vertex, VX00-745-102, A 12 week, randomized, double-blind, placebo-controlled, dose-ranging study of VX-745 in patients with rheumatoid arthritis, 2001-2002

Hoffman-LaRoche, WA15541c, A double-blind, randomized, placebo controlled study to evaluate the safety and efficacy of Ro32-3555 (Trocade) as adjunct to background antirheumatoid therapy, in preventing structural damage in rheumatoid arthritis, 2000-2002

Knoll, DE020, A multicenter 2 year continuation study of the human anti-TNF antibody D2E7 administered as a subcutaneous injection in patients with rheumatoid arthritis, 2001-

Proctor and Gamble, The effect of testosterone patch on activity of systemic lupus erythematosus, 2001-

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A Multi national, Multi center, randomized, double blind, placebo controlled, multiple dose, four arm study to assess the efficacy, tolerability and safety, of three different doses of Edratide (TV-4710) Subcutaneous injections in SLE patients, TEVA 2005-2007

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