

Trial Nation

Clinical Trials Denmark

A network of Danish dermatology departments

Your clinical research partner within dermatology,
allergy, wound healing, and venereology

Trial Nation Dermatology

Trial Nation Center for Dermatology is a network of Danish dermatology departments involved in clinical research within the areas of dermatology, allergy, venereology, auto-immunity and wound healing.

The five departments in Center for Dermatology cover the entire Danish population and treat all types of dermatologic, allergic and venereologic diseases and have more than 250,000 consultations yearly. The Center's doctors, nurses, laboratory technicians and

pharmacists are all trained in clinical research and ensure the highest possible quality in the execution of clinical trials.

National Experimental Therapy Partnership (NEXT) established the center in 2015 and the center was continued as a Trial Nation clinical research center in 2018.

Trial Nation offers one point of contact to the network of hospital departments for research collaboration on clinical trials.

Trial Nation Dermatology Departments

The dermatology departments constituting the Trial Nation Dermatology network collaborate on:

- Clinical trial feasibilities
- Execution of GCP monitored clinical trials
- Study start up including contract negotiation, IRB approval etc.
- Patient recruitment initiatives
- National and site specific databases of patients interested in participating in clinical research
- Involving patient organizations in clinical research
- Investigator initiated research



DANISH UNIVERSITY CLINICS IN TRIAL NATION DERMATOLOGY_REGION	
Department of Dermato-Venereology, Bispebjerg University Hospital	Capital Region of Denmark
Department of Dermatology and Allergy, Gentofte University Hospital	Capital Region of Denmark
Department of Dermatology, Zealand University Hospital Roskilde	Region Zealand
Department of Dermatology and Allergy Centre, Odense University Hospital	The Region of Southern Denmark
Department of Dermatology and Venereology, Aarhus University Hospital	Central Denmark Region
Department of Dermatology and Venereology, Aalborg University Hospital	Northern Denmark Region

The departments recruit patients for clinical trials within a broad range of dermatologic, allergic and venereologic diseases. Some departments have highly specialized functions and treat all patients in Denmark with specific rare diseases.

Experience with clinical trials, research interest and specific research competencies vary across the departments.

Center services

Department	Patients	Databases	Clinical trial experience	Specific research competencies	Contact for trials
Department of Dermato-Venereology, Bispebjerg University Hospital	AD, CL, CSU, CU, EC, HS, LE, PSO, SC, SS, VE	PSO, AD, HS, CSU, SS, SC, CU	Phase I, II, III, IV Incl. FIH, Med-Tech	Photodynamic therapy Laser Surgery Confocal microscopy Patient Reported outcomes Virtual clinical trials	Professor, Chief consultant Simon Francis Thomsen Simon.francis.thomsen.02@regionh.dk
Department of Dermatology and Allergy, Gentofte University Hospital	AA, AD, CSU, GD, HH, LE, PSO, RO, SC	AD, PSO	Phase Ib, II, III, IV	Inflammatory skin diseases: <ul style="list-style-type: none"> • Pathogenesis • Risk factors • Comorbidities • Epidemiology • Quality of care and treatment Skin tumors Genodermatosis IgE mediated allergy	Professor, Consultant dermatologist Lone Skov Lone.skov.02@regionh.dk CORGIS – Copenhagen Research Group for Inflammatory Skin
Department of Dermatology, Zealand University Hospital Roskilde	AD, CU, HH, HS, PSO, SC	AD, HS, PSO	Phase Ib, II, III, IV Incl. Med-Tech, OMI development	Medical dermatology: <ul style="list-style-type: none"> • Pathogenesis • Risk factors • Comorbidities • Epidemiology • Quality of care and treatment Skin tumors Clinimetrics	Professor, Chief consultant Gregor Jemec gbj@regionsjaelland.dk
Department of Dermatology and Allergy Centre, Odense University Hospital	AD, CU, CSU, EC, GD, HAE, HH, HS, LE, PSO, SC, SB, VE	AD, HAE, HH, PSO, SB	Phase Ib, II, III, IV	Adherence, response to treatment, quality of life Contact dermatitis and contact allergy Cutaneous lupus erythematosus Genodermatoses Hyperhidrosis Scabies Skin cancer Pyoderma gangrenosum Pediatric dermatology Teledermoscopy Rare genodermatoses (biobank)	Professor, Chief consultant Charlotte Gotthard Mørtz charlotte.moertz@rsyd.dk
Department of Dermatology and Venereology, Aarhus University Hospital	AD, PSO	AD, PSO	Phase Ib, II, III, IV	Inflammatory dermatoses: <ul style="list-style-type: none"> • Pathogenesis of psoriasis • Atopic dermatitis • Epidemiology Co-morbidities in psoriasis National center for Autoimmune disease	Professor, Chief Consultant Mette Deleuran metdele@rm.dk
Department of Dermatology and Venereology, Aalborg University Hospital	AD, PSO, HS, SC	AD, PSO	Ph II, III, IV	Inflammatory skin diseases clinical research : <ul style="list-style-type: none"> • psoriasis • Atopic dermatitis Hidradenitis suppurativa <ul style="list-style-type: none"> • Epidemiology Co-morbidities in psoriasis Skin cancer	Consultant Kasper Fjellhaugen Hjuler kf.hjuler@m.dk

Note: AA = alopecia areata; AD = atopic dermatitis; CL =cutaneous lymphomas; CSU = chronic urticaria; CU = chronic ulcers; EC = Eczema; GD=genodermatoses; HAE= hereditary angioedema; HH = Hyperhidrosis; HS = hidradenitis suppurativa; LE = lupus erythematosus; OMI = Outcome Measurement Instruments; PSO = psoriasis; RO=Rosacea; SB=Scabies; SC = skin cancer; SS = systemic sclerosis; VE = venereology.

DERMBIO register

The Danish cohort of psoriasis patients treated with biologic agents (DERMBIO) is a national quality and research database established in 2007. It contains information about all psoriasis patients receiving immunomodulatory treatment. It is used to monitor whether the indication for use of 2nd generation immunomodulatory drugs is comparable among the Danish sites approved for prescription of immunomodulatory treatment. The therapeutic quality is monitored at each site i.e. frequency of visits and effect of treatment (PASI, DLQI) Several scientific projects have used data from DERMBIO, and DERMBIO is part of the Psonet (European surveillance network to monitor the long term effectiveness and safety of systemic agents in the treatment of psoriasis). DERMBIO contributes with the second largest number of patients to the network. A similar register for immune-modulatory treatment of atopic dermatitis patients will be initiated during 2019.

For coordinated request to all clinics, please contact

Stine Ørts Petersen, Bispebjerg Hospital
stine.oerts.pedersen@regionh.dk,
+45 21 29 93 49

Kirsten Bødker, Center facilitator
kib@trialnation.dk
+45 40850853

Updates regarding Trial Nation Dermatology are posted on:

- www.trialnation.dk
- www.linkedin.com/in/trialnation

References

- Anette Bygum, Establishing a clinical trial unit in Dermato-Venerology at Odense University Hospital, Denmark, *Forum for Nord Derm Ven*, 2018, vol 23 no 3. 67-73
- Iversen L, Deleuran M. Dermato-Venereological Research at Aarhus University Hospital, *Forum for Nord Derm Ven* 2011 vol 16 no 4 118-119
- Skov L, Thyssen J, Johansen JD. Dermatological Research at Herlev and Gentofte Hospital, University of Copenhagen, *Forum for Nord Derm Ven* 2018, vol 23 no 2 41-43
- Thomsen SF, Hædersdal M, Agner T, Wulf HC, Serup J, Gniadecke R. Bispebjerg Hospital, Department of Dermato-Venereology: Current and Future Research Activities, *Forum for Nord Derm Ven* 2018 vol 23 no 1 8-12.
- Leonardi C, Matheson R, Zachariae C, Cameron G, Li L, Edson-Heredia E, Braun D, Banerjee S. Anti-interleukin-17 monoclonal antibody ixekizumab in chronic plaque psoriasis. *N Engl J Med*. 2012 Mar 29;366(13):1190-9.
- Todberg T, Zachariae C, Bregnhøj A, Hedelund L, Bonefeld KK, Nielsen K, Iversen L, Skov L. The effect of botulinum neurotoxin A in patients with plaque psoriasis - an exploratory trial. *J Eur Acad Dermatol Venereol*. 2018 Feb;32(2):e81-e82.
- Egeberg A, Ottosen MB, Gniadecki R, Broesby-Olsen S, Dam TN, Bryld LE, Rasmussen MK, Skov L. Safety, efficacy and drug survival of biologics and biosimilars for moderate-to-severe plaque psoriasis. *Br J Dermatol*. 2018 Feb;178(2):509-519.
- Jemec GB. Clinical practice. Hidradenitis suppurativa. *N Engl J Med*. 2012 Jan 12;366(2):158-64. doi: 10.1056/NEJMcp1014163. Review. PubMed PMID: 22236226.
- Zouboulis CC, Bechara FG, Dickinson-Blok JL, Gulliver W, Horváth B, Hughes R, Kimball AB, Kirby B, Martorell A, Podda M, Prens EP, Ring HC, Tzellos T, van der Zee HH, van Straalen KR, Vossen ARJV, Jemec GBE. Hidradenitis suppurativa/acne inversa: a practical framework for treatment optimization - systematic review and recommendations from the HS ALLIANCE working group. *J Eur Acad Dermatol Venereol*. 2019 Jan;33(1):19-31. doi: 10.1111/jdv.15233. Epub 2018 Oct 23. PubMed PMID: 30176066.
- Zouboulis CC, Desai N, Emtestam L, Hunger RE, Ioannides D, Juhász I, Lapins J, Matusiak L, Prens EP, Revuz J, Schneider-Burrus S, Szepletowski JC, van der Zee HH, Jemec GB. European S1 guideline for the treatment of hidradenitis suppurativa/acne inversa. *J Eur Acad Dermatol Venereol*. 2015 Apr;29(4):619-44. doi: 10.1111/jdv.12966. Epub 2015 Jan 30. PubMed PMID: 25640693.
- Thorlacius L, Garg A, Riis PT, Nielsen SM, Bettoli V, Ingram JR, Del Marmol V, Matusiak L, Pascual JC, Revuz J, Sartorius K, Tzellos T, van der Zee HH, Zouboulis CC, Saunte DM, Gottlieb AB, Christensen R, Jemec GBE. Inter-rater agreement and reliability of outcome measurement instruments and staging systems used in hidradenitis suppurativa. *Br J Dermatol*. 2019 Feb 6. doi:10.1111/bjd.17716. [Epub ahead of print] PubMed PMID: 30724351.
- Thorlacius L, Ingram JR, Villumsen B, Esmann S, Kirby JS, Gottlieb AB, Merola JF, Dellavalle R, Nielsen SM, Christensen R, Garg A, Jemec GBE; Hidradenitis Suppurativa cORe outcomes set International Collaboration (HISTORIC). A core domain set for hidradenitis suppurativa trial outcomes: an international Delphi process. *Br J Dermatol*. 2018 Sep;179(3):642-650. doi: 10.1111/bjd.16672. Epub 2018 Jul 5. PubMed PMID: 29654696; PubMed Central PMCID: PMC6141318.
- Lindsø Andersen P, Olsen J, Friis KBE, Themstrup L, Grandahl K, Mortensen OS, Jemec GBE. Vascular morphology in normal skin studied with dynamic optical coherence tomography. *Exp Dermatol*. 2018 Sep;27(9):966-972. doi: 10.1111/exd.13680. Epub 2018 Aug 3. PubMed PMID: 29733465.
- Olsen J, Holmes J, Jemec GB. Advances in optical coherence tomography in dermatology-a review. *J Biomed Opt*. 2018 Apr;23(4):1-10. doi: 10.1117/1.JBO.23.4.040901. PubMed PMID: 29701018.

Themstrup L, De Carvalho N, Nielsen SM, Olsen J, Ciardo S, Schuh S, Nørnberg BM, Welzel J, Ulrich M, Pellacani G, Jemec GBE. In vivo differentiation of common basal cell carcinoma subtypes by microvascular and structural imaging using dynamic optical coherence tomography. *Exp Dermatol*. 2018 Feb;27(2):156-165. doi: 10.1111/exd.13479. Epub 2018 Jan 10. PubMed PMID: 29215761.

Olsen J, Themstrup L, De Carvalho N, Mogensen M, Pellacani G, Jemec GB. Diagnostic accuracy of optical coherence tomography in actinic keratosis and basal cell carcinoma. *Photodiagnosis Photodyn Ther*. 2016 Dec;16:44-49. doi: 10.1016/j.pdpdt.2016.08.004. Epub 2016 Aug 9. PubMed PMID: 27519350.

Esmann S, Vinding GR, Christensen KB, Jemec GB. Assessing the influence of actinic keratosis on patients' quality of life: the AKQoL questionnaire. *Br J Dermatol*. 2013 Feb;168(2):277-83. doi: 10.1111/bjd.12036. Review. Erratum in: *Br J Dermatol*. 2013 Apr;168(4):914. PubMed PMID: 22962980.

Vinding GR, Christensen KB, Esmann S, Olesen AB, Jemec GB. Quality of life in non-melanoma skin cancer--the skin cancer quality of life (SCQoL) questionnaire. *Dermatol Surg*. 2013 Dec;39(12):1784-93. doi: 10.1111/dsu.12353. Epub 2013 Nov 14. PubMed PMID: 24237851.

Trial Nation

Get in touch

www.trialnation.dk

contact@trialnation.dk

+45 20 22 42 38