

# Wetenschappelijk onderzoek van 1 april tot en met 31 oktober 2023

**Wetenschappelijk onderzoek goedgekeurd door de Raad van Bestuur in de periode 1 april tot en met 31 oktober 2023 (een deel van de lijst is ook terug te vinden op www.Clinicaltrial.gov of in het Nederlands trialregister). De vetgedrukte titels betreffen onderzoeken in Rijnstate geïnitieerd.**

## Allergie Centrum

**Allergeniciteit Gly m4. Allergeniciteit van diverse vormen van Gly m4 bij boompollen en Gly m4 IgE gesensibiliseerde patiënten.** Monocenter studie. Lokale hoofdonderzoeker: Janneke Ruinemans-Koerts

## Acute Opname Afdeling

Resilience measurements at the Acute Medical Unit. Evaluating the feasibility of measuring resilience in older patients admitted to the Acute Medical Unit. Multicenter studie. Lokale hoofdonderzoeker: Frank Bosch

## Cardiologie

Voed je beter (interventiestudie voor diabetes 2). The effects of personalized dietary guidance to increase the intake of fibre-rich foods on cardiometabolic risk profile in individuals with type 2 diabetes. Multicenter studie. Lokale hoofdonderzoeker: Ron Pisters

NORshock. Clinical Outcome and Cost-effectiveness of Reduced Noradrenaline by Using a Lower Blood Pressure Target in Patients with Cardiogenic Shock from Acute Myocardial Infarction. Multicenter studie. Lokale hoofdonderzoeker: Ron Pisters

NL-CFT (registratie). Dutch Coronary Function Test Registry in patients with Ischemia and Non obstructive Coronary Arteries. Multicenter studie. Lokale hoofdonderzoeker: Stijn van den Oord CKJX839D12302 VICTORION-1 PREVENT. A randomized, double-blind, placebo-controlled multi center study to evaluate the effect of inclisiran on preventing major adverse cardiovascular events in high-risk primary prevention patients. Multicenter studie. Lokale hoofdonderzoeker: Hans van Rees

SIT LESS LONG TERM. Lange termijn effecten van zit- en beweeggedrag op cardiovasculaire events en vroegtijdige sterfte bij patiënten met hart- en vaatziekten. Multicenter studie. Lokale hoofdonderzoeker: Ron Pisters

Hybrid DEB study + registratie. Bifurcation PCI with a hybrid strategy with drug eluting balloons versus a conventional two-stent strategy. Multicenter studie. Lokale hoofdonderzoeker: Hans van Rees

## CBT/MKA

**ELONA. The Effect of Le Fort I Orthognathic Surgery on the Nose Aesthetics.** Monocenter studie. Lokale hoofdonderzoeker: Hossein Ghaeminia

## Geriatrie

PNOM Implementation. Palliative NonOperative Management

(PNOM) in selected elderly with a limited life expectancy who sustained a proximal femoral fracture (PNOMImplementation); an implementation study. Multicenter studie. Lokale hoofdonderzoeker: Hugo Wijnen

PENG PHENOL RETRO. Lessons learned: PENG block with phenol in geriatric patients receiving palliative non-operative management, a multicenter retrospective cohort study. Multicenter studie. Lokale hoofdonderzoeker: Hugo Wijnen

## Gynaecologie

Promote-P study. Prediction of Response Of horMOnal Treatment in advanced and recurrent Endometrial cancer (PROMOTE-study). Multicenter studie. Lokale hoofdonderzoeker: Paul Dijkhuizen SLIM-S. Sentinel node biopsy in Low- and Intermediate-risk endometrial cancer Management: Survival (SLIM-S). Multicenter studie. Lokale hoofdonderzoeker: Tijmen Bonestroo

**Opsporen erfelijkheid ovariumcarcinoom. Het opsporen van erfelijke varianten van ovariumcarcinoom in een groot opleidingsziekenhuis in Nederland. De invloed van de richtlijn familiair ovariumcarcinoom en de introductie van ‘tumor first’.** Monocenter studie. Lokale hoofdonderzoeker: Alexandra van Ginkel

## IC/MC

Safety 2. Zorgvuldige en veilige transitie van IC-patiënten naar de verpleegafdeling. Leren en verbeteren op basis van ‘work as done’ en succeservaringen van patiënten, naasten en professionals. Multicenter studie. Lokale hoofdonderzoeker: Birgitte Westerhof

Weaning with tracheostomy . Weaning from Invasive Mechanical Ventilation with Tracheostomy – an Observational Study focusing on patient-centred Outcomes. Multicenter studie. Lokale hoofdonderzoeker: Evelien Oostdijk

## Interne geneeskunde

DARE. Dual hormone closed loop in type 1 diabetes mellitus: a randomized trial (DARE). Multicenter studie. Lokale hoofdonderzoeker: Arianne van Bon

ISIS 678354-CS9 Essence. A Randomized, Double-blind, Placebo-Controlled, Phase 3 Study of Olezarsen (ISIS 678354) in Patients with Hypertriglyceridemia and Atherosclerotic Cardiovascular Disease (Established or at Increased Risk for), or with Severe Hypertriglyceridemia. Multicenter studie. Lokale hoofdonderzoeker: Houshang Monajemi

Predict-prospective. Percutaneous peritoneal dialysis catheter insertion. Multicenter studie. Lokale hoofdonderzoeker: Jacobien Verhave

DREAM 1. Delta hepatitis: epidemiology and treatment in the Netherlands. Multicenter studie. Lokale hoofdonderzoeker: Mark Claassen

**Tijdstip blaaskatheter verwijderen. Het ideale tijdstip van het verwijderen van een blaaskatheter bij volwassen patiënten opgenomen in het ziekenhuis.** Monocenter studie. Lokale hoofdonderzoeker: Frank Bosch

#### **Kindergeneeskunde**

Coeliakie bij IgA-deficiëntie. Multicenter studie. Lokale hoofdonderzoeker: Margreet Wessels

Onderzoek naar antibiotica gebruik bij neonaten NL. Incidence of early onset sepsis (EOS) and antibiotic exposure in the Netherlands, a retrospective, multi-center cross-sectional study between 2019 and 2021. Multicenter studie. Lokale hoofdonderzoeker: Maaike van Rossem

OxyKids. Safe, effective and cost-effective oxygen saturation targets for children and adolescents with respiratory distress: a randomized controlled trial. Multicenter studie. Lokale hoofdonderzoeker: Mirjam Scheffer

CD-in focus. ESPGHAN study on clinical presentation and current status of management of CD across Europe. Multicenter studie. Lokale hoofdonderzoeker: Margreet Wessels

#### **KNO, Plastische chirurgie**

ROSLIE. Risk factors and Occurrence of Small vessel disease in Acute sensorineural hearing Loss In Elderly. Multicenter studie. Lokale hoofdonderzoeker: Henk Bouman

Eminent. Early Mucosal Immunity in ENT samples. Multicenter studie. Lokale hoofdonderzoeker: Caroline Verhagen

#### **Longgeneeskunde**

Influenza-studie (Grip op griep). Het opstellen en valideren van een klinisch predictiemodel voor de prognose van influenzavirus. Multicenter studie. Lokale hoofdonderzoeker: Peter de Jong

BUS-P3-01 (CALM-1). A Phase 3, 52-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm Efficacy and Safety Study with Open-Label Extension of BLU-5937 in Adult Participants with Refractory Chronic Cough, Including Unexplained Chronic Cough. Multicenter studie. Lokale hoofdonderzoeker: Marjo van de Ven

#### **MDL**

OVI-IBD. Oral versus intravenous iron in IBD patients with anti-inflammatory therapy. Multicenter studie. Lokale hoofdonderzoeker: Carmen Horjus - Talabur Horje

**GATE trial. The GATE trial: Endoscopic sutured Gastroplasty in Type 2 diabetic, obese patients using the Endomina device – a randomized controlled trial.** Monocenter studie. Lokale hoofdonderzoeker: Marcel Groenen

**Risico kenmerken SBP bij levercirrose. Een kwantitatief patient control onderzoek om te achterhalen hoeveel patiënten met ascites als gevolg van levercirrose ondanks het ophogen van diuretica een SBP hebben en welke verschillende**

**kenmerken hierbij een rol spelen.** Monocenter studie. Lokale hoofdonderzoeker: Jan Maarten Vrolijk

#### **MIL**

ENPEN - NPEV-associated neurological infections. ENPEN - disease burden of Non-Polio Enteroviruses-associated neurological infection and infections in the central nervous system. Multicenter studie. Lokale hoofdonderzoeker: Jacky Flipse

**Rapid antibiotic resistance tests. A multicenter retrospective study evaluating the diagnostic characteristics of two different rapid antibiotic resistance tests on direct urine in patients with a or suspicious for a complicated urinary tract infection.** Multicenter studie. Lokale hoofdonderzoeker: Sabien Bongers

#### **Neurologie**

BROCA intervention. Multicenter studie. Lokale hoofdonderzoeker: Jeannette Hofmeijer

Noisy Rebels. Non-inferiority study of rituximab compared to ocrelizumab in relapsing MS. Multicenter studie. Lokale hoofdonderzoeker: Jop Mostert

CASES. Carotid Artery Stenting during Endovascular treatment of acute ischemic Stroke (CASES) versus deferred treatment of carotid artery stenosis. Multicenter studie. Lokale hoofdonderzoeker: Jeannette Hofmeijer

CT-perfusie studie. De CT-cerebrum perfusie scan (CTP) als voor-speller voor een slecht functioneel resultaat en complicaties na intraveneuze trombolyse (IVT) en/of intra-arteriële trombectomie (IAT) bij patiënten met een acuut ischemisch CVA: een retrospectieve multicenter studie. Multicenter studie. Lokale hoofdonderzoeker: Sarah Vermeer

Computeranalyse van het EEG. Beste EEG Strategie voor de dagelijkse praktijk (BEST). Multicenter studie. Lokale hoofdonderzoeker: Hanneke Keijzer

#### **OKC**

**Respiratory Rate – HFNC. Is it possible to measure an adequate respiration rate using pressure variation during HFNC?** Monocenter studie. Lokale hoofdonderzoeker: Mark Koning

#### **Oncologisch centrum**

Hovon 164. Tisleizumab plus Gemcitabine and Cisplatin for Relapsed or Refractory Hodgkin Lymphoma followed by Tisleizumab Consolidation in Patients in Metabolic Complete Remission (TIGERR-HL). An open label phase II trial. Multicenter studie. Lokale hoofdonderzoeker: Wendy Deenik

NABOR study. Effectiveness of personalized care After treatment for nonmetastasized Breast cancer based On risk of Recurrence, personal needs and risk on (late) health effects: the NABOR study. Multicenter studie. Lokale hoofdonderzoeker: Ramon van Eekeren

# Wetenschappelijk onderzoek van 1 april tot en met 31 oktober 2023

N-CIA study (biobank). The Netherlands facility for Cancer-Immune Analysis (N-CIA): studying interaction between immune factors of the tumor and the host. Multicenter studie. Lokale hoofdonderzoeker: Rutger Koornstra

Right study - part 2. Implementation of optimized and standardized surgical technique for right-sided colon cancer: a prospective interventional sequential cohort study with a transition period. Multicenter studie. Lokale hoofdonderzoeker: Marnix de Roos

SAUNA. Continuing Somatostatin Analogues Upon progression in Neuroendocrine tumour pAtients. Multicenter studie. Lokale hoofdonderzoeker: Theo van Voorthuizen

SEARCH trial. Safely reduce cystoscopic evaluation for microscopic hematuria patients (SeARCH-trial). Multicenter studie. Lokale hoofdonderzoeker: Carl Wijburg

INSIGHT study. Improving Nationwide Survivorship care Infrastructure and Guidelines after Hodgkin lymphoma Treatment (INSIGHT). Multicenter studie. Lokale hoofdonderzoeker: Wendy Deenik

ALIDHE. A single arm, open-label Phase 3b study to describe the safety and tolerability of ivosidenib in combination with azacitidine in adult patients newly diagnosed with IDH1m acute myeloid leukemia (AML) ineligible for intensive induction chemotherapy. Multicenter studie. Lokale hoofdonderzoeker: Marloes Cuijpers

Eva2ROMIC. Role Of Ovarian Metastases In Colorectal Cancer (ROMIC): study protocol to valuate the effect of prophylactic salpingo-oophorectomy in postmenopausal women in the Netherlands. Multicenter studie. Lokale hoofdonderzoeker: Marnix de Roos

DECIDE snapshot. Immediate Breast Reconstruction after Mastectomy in the Netherlands - DECIDE snapshot. Multicenter studie. Lokale hoofdonderzoeker: Ramon van Eekeren

**VTE na CRC resecties. Evaluatie van veneuze trombo-embolie profylaxe bij chirurgie voor colorectaal carcinoom.**  
Monocenter studie. Lokale hoofdonderzoeker: Stijn van Cruchten

## Pathologie

**Variability in oral dysplasia reporting. Interobserver en intraobserver variability in reporting dysplasias and leucoplakias and the prognostic significance of dysplastic criteria.**  
Multicenter studie. Lokale hoofdonderzoeker: Marc Ooft

## Pijncentrum

Peng. The effect of the modified PENG block in patients with a hip fracture who are not eligible for surgery: a prospective multicentred cohort study. Multicenter studie. Lokale hoofdonderzoeker: Jan-Willem Kallewaard

**Cervical lead. Assessment of effectiveness and stimulation coverage of closed-loop spinal cord stimulation (CL-SCS) therapy in patients with cervical lead placement.** Multicenter studie. Lokale hoofdonderzoeker: Jan-Willem Kallewaard

**rapy in patients with cervical lead placement.** Multicenter studie. Lokale hoofdonderzoeker: Jan-Willem Kallewaard

## Preventie/gezondheidsplein

**Personalized health advice. The relation between personal characteristics and the recommendation of a secondary prevention intervention: A regression analysis.** Monocenter studie. Lokale hoofdonderzoeker: Wim van Harten

**HealthGuide: Automated guidance for secondary prevention, a digital system for social and health services.** Monocenter studie. Lokale hoofdonderzoeker: Wim van Harten

## Psychosociale Zorg en Zingeving

**Inventarisatie geheugenzorgen, slaap en stemming. Inventarisatie geheugenzorgen en de relatie met slaap en stemming, bij patienten verwezen voor neuropsychologisch onderzoek.** Monocenter studie. Lokale hoofdonderzoeker: Rubia Bloo

## Radiologie en Nucleaire geneeskunde

**MISTIC-CT. Voorbereidende CT studie voor de studie MRI and cineMRI to Improve Staging of Tumors of the Colon.** Multicenter studie. Lokale hoofdonderzoeker: Josephine Huige

**I131 dosisberekening met SPECT/CT. I131 dosisberekening met SPECT/CT in vergelijking met planaire scintigrafie.**  
Monocenter studie. Lokale hoofdonderzoeker: Femke Intema

**Fase reductie 4DCT protocol. Multireader multicase studie voor reductie van fases in het 4DCT protocol.** Monocenter studie. Lokale hoofdonderzoeker: Jorian Krol

## Reumatologie

**REDUCE PMR 2 relapse. REDUCE PMR: Rituximab Effect on Decreasing glUcoCorticoid Exposition in relapsing PolyMyalgia Rheumatica.** Multicenter studie. Lokale hoofdonderzoeker: Amanda Branten

**REDUCE PMR 1. REDUCE PMR-1: Rituximab Effect on Decreasing glUcoCorticoid Exposition in newly diagnosed PolyMyalgia Rheumatica.** Multicenter studie. Lokale hoofdonderzoeker: Amanda Branten

## SEH

**Ultrasound-guided arterial puncture. Comparison of 3 Different Ultrasound-Guided Radial Artery Puncture Techniques for Blood Gas Analysis in Emergency Department Patients: a Flash-Mob Trial.** Multicenter studie. Lokale hoofdonderzoeker: Nicole Langhout

## Traumatologie

**Complicaties Gekruiste en laterale K-draad fixatie. Complications after lateral versus crossed K-wire fixation of supracondylar fractures in children: a retrospective cohort study.** Monocenter studie. Lokale hoofdonderzoeker: Stijn van Cruchten

## Vasculair Centrum

**HERCULES TRIAL. Randomized controlled clinical trial on the application of Heli-FX EndoAnchors in conjunction with the Endurant II/IIs endograft in infrarenal aortic aneurysms with a wide infrarenal neck.** Multicenter studie. Lokale hoofdonderzoeker: Michel Reijnen

OCEAN(a). A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Olpasiran on Major Cardiovascular Events in Patients with Atherosclerotic Cardiovascular Disease and Elevated Lipoprotein (a) 20180244. Multicenter studie. Lokale hoofdonderzoeker: Houshang Monajemi

Preserve. Gentamicin-loaded calcium sulfate - hydroxyapatite bio-composite to treat diabetic foot ulcers complicated by osteomyelitis: a prospective cohort study (PRESERVE). Multicenter studie. Lokale hoofdonderzoeker: Luuk Smeets

**US after EVAR. 3D ultrasound for postoperative surveillance of abdominal aortic aneurysm after endovascular repair (3D US after EVAR).** Monocenter studie. Lokale hoofdonderzoeker: Michel Reijnen

**Anatomie van de infrarenale nek voor en na EVAR. Relatie tussen de anatomie van de infrarenale aorta nek en complicaties na EVAR.** Monocenter studie. Lokale hoofdonderzoeker: Michel Reijnen

NYU IMPEDE study. Evaluation of outcomes after aortic or aortoiliac aneurysm sac management with shape memory polymer IMPEDE-FX embolization plugs in patients undergoing EVAR. Multicenter studie. Lokale hoofdonderzoeker: Michel Reijnen

## Vitalys

**BEAT-IT. Bariatric surgery Evaluation and Assessment of Treatment efficacy heart failure and preserved ejection fraction - Intervention Trial.** Multicenter studie. Lokale hoofdonderzoeker: Eric Hazebroek

**3D IH. 3D reconstructie bij inwendige herniatie.** Monocenter studie. Lokale hoofdonderzoeker: Eric Hazebroek

**Evaluatie vitale parameters dagbehandeling. De invloed van vitale parameters, gemeten door een wearable sensor, op de klinische besluitvorming bij patiënten na bariatrische chirurgie in dagbehandeling, middels een nationale survey en beschrijving van eerste 165 patiënten in dagbehandeling.** Monocenter studie. Lokale hoofdonderzoeker: Eric Hazebroek

**Extended Pouch trial: 8-9 jaar resultaten. Extended versus standard pouch in Roux-en-Y gastric bypass: 8-9 year results of a randomized controlled trial.** Monocenter studie. Lokale hoofdonderzoeker: Eric Hazebroek

## Wetenschapsbureau

Mentale en fysieke gezondheid na Covid-19. De mentale en fysieke gezondheid na een COVID-19 besmetting bij personen met en zonder opname in het ziekenhuis. Multicenter studie. Lokale hoofdonderzoeker: Simone Croezen

# Publicaties april 2023 t/m oktober 2023

Admiraal M, Hermanides J, Meinsma SL, Wartenberg HCH, Rutten MVH, Heine Y, Kallewaard JW, Hollmann MW, Hermanns H. *The effectiveness of a transitional pain service in patients undergoing surgery with an increased risk of developing chronic postsurgical pain (TRUST study). A randomized clinical trial.* J Clin Anesth. 2023;91:111262.

Admiraal M, van Zuylen ML, Hermanns H, Willems HC, Geurtsen GJ, Steegers MAH, Kallewaard JW, Hollmann MW, Hermanides J. *The Effect of Preoperative Disability, Cognitive Impairment, Frailty and Opioid Use on Acute Postoperative Pain in Older Patients Undergoing Surgery A Prospective Cohort Study.* The journal of pain : official journal of the American Pain Society. 2023;24(10):1886-95.

Admiraal MM, van Merkerk M, Horn J, Koelman J, Hofmeijer J, Hoedemaekers CW, van Rootselaar AF. *EEG in a four-electrode frontotemporal montage reliably predicts outcome after cardiac arrest.* Resuscitation. 2023;188:109817.

Ågren R, Geerdink N, Brunner HG, Paucar M, Kamsteeg EJ, Sahlholm K. *An E280K Missense Variant in KCND3/Kv4.3-Case Report and Functional Characterization.* Int J Mol Sci. 2023;24(13).

Al-Shahi Salman R, Stephen J, Tierney JF, Lewis SC, Newby DE, Parry-Jones AR, White PM, Connolly SJ, Benavente OR, Dowlatshahi D, Cordonnier C, Viscoli CM, Sheth KN, Kamel H, Veltkamp R, Larsen KT, Hofmeijer J, Kerkhoff H, Schreuder F, Shoamanesh A, Klijn CJM, van der Worp HB. *Effects of oral anticoagulation in people with atrial fibrillation after spontaneous intracranial haemorrhage (COCROACH): prospective, individual participant data meta-analysis of randomised trials.* Lancet Neurol. 2023.

Aleman BMP, Ricardi U, van der Maazen RWM, Meijnders P, Beijert M, Boros A, Izar F, Janus CPM, Levis M, Martin V, Specht L, Corning C, Clementel E, Raemaekers JM, André MP, Federico M, Fortpied C, Girinsky T. *A Quality Control Study on Involved Node Radiation Therapy in the European Organisation for Research and Treatment of Cancer/Lymphoma Study Association/Fondazione Italiana Linfomi H10 Trial on Stages I and II Hodgkin Lymphoma: Lessons Learned.* Int J Radiat Oncol Biol Phys. 2023;117(3):664-74.

Amini M, Eijkenaar F, Lingsma HF, den Hartog SJ, Olthuis SGH, Martens J, van der Worp B, van Zwam W, van der Hoorn A, Roosendaal SD, Roozenbeek B, Dippel D, van Leeuwen N. *Validity of Early Outcomes as Indicators for Comparing Hospitals on Quality of Stroke Care.* J Am Heart Assoc. 2023;12(8):e027647.

Amorim E, Zheng WL, Ghassemi MM, Aghaeaval M, Kandhare P, Karukonda V, Lee JW, Herman ST, Sivaraju A, Gaspard N, Hofmeijer J, van Putten M, Sameni R, Reyna MA, Clifford GD, Westover MB. *The International Cardiac Arrest Research Consortium Electroencephalography Database.* Crit Care Med. 2023.

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ter Avest MM, van Velthoven ASM, Speckens AEM, Dijkstra G, Dresler M, Horjus CS, Römkens TEH, Witteman EM, van Dop WA,

Bredero QM, Nissen LHC, Huijbers MJ. *Effectiveness of Mindfulness-Based Cognitive Therapy in reducing psychological distress and improving sleep in patients with Inflammatory Bowel Disease: study protocol for a multicentre randomised controlled trial (MindIBD).* BMC Psychol. 2023;11(1):183.

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van den Beukel BAW, de Wilde B, Joosten F, van Goor H, Venderink W, Huisman HJ, Ten Broek RPG. *Quantifiable Measures of Abdominal Wall Motion for Quality Assessment of Cine-MRI Slices in Detection of Abdominal Adhesions.* J Imaging. 2023;9(5).

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Blans MJ, Strang A. *Fresh air for intensive care patients in the Netherlands: an example to be followed?* Intensive Care Med. 2023.

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Bruin WB, Oltedal L, Bartsch H, Abbott C, Argyelan M, Barbour T, Camprodron J, Chowdhury S, Espinoza R, Mulders P, Narr K, Oudega M, Rhebergen D, Ten Doesschate F, Tendolkar I, van Eijndhoven P, van Exel E, van Verseveld M, Wade B, van Waarde J, Zhutovsky P, Dols A, van Wingen G. *Development and validation of a multimodal*

*neuroimaging biomarker for electroconvulsive therapy outcome in depression: a multicenter machine learning analysis.* Psychol Med. 2023;1-12.

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