

Onderzoek goedgekeurd door de RvB in de periode mei - augustus 2022 (St. Antonius Ziekenhuis)

| Acroniem | Studietitel | Hoofdonderzoeker | Afdeling | Monocenter/ Multicenter | eigen geïnitieerd | WMO plichtig? |
|--|--|-------------------|------------------------------------|----------------------------|----------------------|------------------|
| TRACE-NL | Evaluation of the safety, efficacy and cost-effectiveness of transcatheter tricuspid valve repair in patients with severe tricuspid regurgitation in the Netherlands | Timmers, L. | Cardiologie | Multicenter | Ja | Ja |
| GUIDE-SAVR | Preoperative chest CT-imaging in surgical aortic valve replacement with or without CABG: a randomized controlled trial | Klein, P. | Cardio-thoracale chirurgie | Q4 2022 | Ja | Ja |
| AQUIOS heup studie | Automated Fast Analysis of Neutrophil Phenotype in Geriatric Hip Fracture Patients | Velde van der, D. | Chirurgie/heelkunde | Monocenter | Ja | Ja |
| INFLUENCE II | Identification of sentinel lymph nodes in breast cancer patients through non-invasively fluorescent imaging using indocyanine green: a multicentre implementation study | Doeksen, A. | Heelkunde | Multicenter | Ja | Ja |
| ULTRA-ERAS | ULTRA-ERAS: discharge after 24hours after colorectal surgery, a pilot study | Smits, A.B. | Heelkunde | Monocenter | Ja | Ja |
| GILDE-trial | De meerwaarde van GGZ-ondersteuning voor patiënten binnen het ILD Expertisecentrum (GILDE-trial) | Helmond van, S.J. | Longziekten | Monocenter | Ja | Ja |
| REMOVE-RCT | Endoscopic mucosal resection versus endosopic submucosal dissection for removal of visible lesions in Barrett's esophagus: a randomized study | Weusten, B.L.A.M. | MDL (maag-, darm- en leverziekten) | Multicenter | Ja | Ja |
| Ticagrelor removal by Cytosorb during CPB | Pilot study for the use of Cytosrb during cardiopulmonary bypass in cardiac surgery patients who have continued the use Ticagrelor. | Stehouwer, M.C. | Anesthesiologie | Monocenter | Ja | Nee |
| Afeqt NHR study | Effect of baseline characteristics and outcomes on quality of life in patients with AF undergoing catheter PVI; Results of a multicentre VBHC project in cardiac diseases in the Netherlands (Afeqt NHR study) | Balt, J.C. | Cardiologie | Multicenter | Ja | Nee |
| AVATAR-FRAME | Capture the value of innovative cardiac care in a practically applicable evaluation framework to facilitate decision-making on meso level (AVATAR-FRAME study Section 1: Development of an evaluation framework) | Garvelink, M.M. | Cardiologie | Monocenter | Ja | Nee |
| VAL-UMARS-NL | Validatie van de 'User Version of the Mobile App Rating Scale' onder 150 Nederlandse participanten. | Doeksen, A. | Chirurgie/heelkunde | Monocenter | Ja | Nee |
| Preferentie studie vaginale prolapsen | A patient preference study of native tissue versus mesh as a treatment for recurrent vaginal prolapses | Klerkx, W.M. | Gynaecologie | Monocenter | Ja | Nee |
| PP-PTA | Peri-procedural Photoplethysmography in Percutaneous Transluminal Angioplasty | Bakker, O.J. | Heelkunde | Monocenter | Ja | Nee |
| Optimalisatie diagnostiek naar inwendige hernia na gastric bypass | Optimizing the diagnostic strategy for the accurate detection of internal herniation following roux-y gastric bypass | Derkzen, W.J.M. | Heelkunde | | Ja | Nee |
| DIRECT | Direct versus Delayed DIEP Reconstruction in the Context of Post-mastectomy Radiation Therapy | Doeksen, A. | Heelkunde | Monocenter | Ja | Nee |
| What are the Goals of Care for geriatric hip fracture patients? | What are the Goals of Care for geriatric hip fracture patients? | Velde van der, D. | Heelkunde | Monocenter | Ja | Nee |
| Designing a decision aid for frail geriatric hip fracture patients: needs assessment | Designing a decision aid for frail geriatric hip fracture patients: needs assessment | Velde van der, D. | Heelkunde | Monocenter | Ja | Nee |
| Bronchoscopie bij COVID-19 | De invloed van bronchoscopie op het beleid bij COVID-19 patiënten | Moeniralam, H. | IC (intensive care) | Monocenter | Ja | Nee |

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| Voorspellers voor het ontstaan van long covid | Voorspellers voor het ontstaan van long covid en verschillen in long covid-klachten, beeldvorming en longfunctie tussen patiënten die wegens covid opgenomen zijn geweest op de ICU versus alleen op de verpleegafdeling. | Moeniralam, H. | Interne geneeskunde | Monocenter | Ja | Nee |
| SIAAK | Salbutamol intraveneus bij kinderen met acuut astma op de kinderafdeling | Balemans, W.A.F. | Kindergeneeskunde | Multicenter | Ja | Nee |
| M-RABAR | Medication-related hospital readmissions after bariatric surgery | Burgers, D. | Klinische farmacie | Monocenter | Ja | Nee |
| | Management van immuungerelateerde bijwerkingen bij solide tumoren | Garde van de, E.M.W. | Klinische farmacie | Multicenter | Ja | Nee |
| Insomnia Inspire | The influence of pre-treatment insomnia on the outcome of Inspire Upper Airway Stimulation | Copper, M.P. | KNO | Monocenter | Ja | Nee |
| VelarCollapseInspire | The effect of velar collapse patterns on Inspire Upper Airway Stimulation | Copper, M.P. | KNO (keel-, neus- en oorheelkunde) | Monocenter | Ja | Nee |
| Pancreas textuur bepalen met CT scan | 'Using Computed Tomography for determining pancreas texture | Lienden van K.P. | Radiologie | Monocenter | Ja | Nee |
| FAPI | Aantonbaarheid van fibroblasten of inflammatie passend bij Peyronie in de penis op een FDG-PET scan gemaakt voor een andere indicatie | Beck, J.J.H. | Urologie | Multicenter | Ja | Nee |
| Superfast diagnostic pathway for prostate cancer analysis | Superfast diagnostic MRI-based pathway for prostate cancer: A process | Bergh van den, R.C.N. | Urologie | Monocenter | Ja | Nee |
| PFCA SC 169 | Adagio Medical Pulsed Field Ablation (PFA) and Pulsed Field Cryoablation (PFCA) Systems for persistent Atrial Fibrillation (PsAF) | Boersma, L.V.A. | Cardiologie | Multicenter | Nee | Ja |
| Hybrid DEB | Bifurcation PCI with a hybrid strategy with drug eluting balloons versus a conventional two-stent strategy. A randomized controlled single-blinded multicenter trial and registry | Kuijk van J.P. | Cardiologie | Multicenter | Nee | Ja |
| EXPAND TAVR II | Evolut™ EXPAND TAVR II Pivotal | Swaans, M. | Cardiologie | Multicenter | Nee | Ja |
| MUSCAT | Multicenter randomized controlled trial on nonoperative versus operative treatment for acute complete tears of the ulnar collateral ligament of the thumb: Cost-effectiveness and functional outcomes (MUSCAT) | Velde van der, D. | Chirurgie/heelkunde | Multicenter | Nee | Ja |
| LUMO | LUTEAL PHASE SUPPORT IN MOH-IUI TREATMENT | Disseldorp van, J. | Gynaecologie | Multicenter | Nee | Ja |
| DESCARTES | DESCARTES trial: De-ESCALating RadioTherapy in patients with pathologic complete rESpone to neoadjuvant systemic therapy | Doeksen, A. | Heelkunde | Multicenter | Nee | Ja |
| Sparrow | Standard versus pre-emptive antibiotic treatment after pancreateoduodenectomy (SPARROW): a multicenter, randomized controlled superiority trial | Santvoort van, H.J. | Heelkunde | Multicenter | Nee | Ja |
| SGNTUC-028 | A randomized, double-blind, phase 3 study of tucatinib or placebo in combination with trastuzumab and pertuzumab as maintenance therapy for metastatic HER2+ breast cancer (HER2CLIMB-05) | Agterof, M.J. | Interne geneeskunde | Multicenter | Nee | Ja |
| SEQUEL Breast | SEQUence of Endocrine therapy in advanced Luminal Breast cancer (SEQUEL- Breast): A phase 2 study on fulvestrant beyond progression in combination with alpelisib for PIK3CA-mutated, hormone-receptor positive HER2 negative advanced breast cancer | Jong de, P.C. | Interne geneeskunde | Multicenter | Nee | Ja |
| Krystal 10 | A Randomized Phase 3 Study of MRTX849 in Combination with Cetuximab Versus Chemotherapy in Patients with Advanced Colorectal Cancer with KRAS G12C Mutation with Disease Progression On or After Standard First-Line Therapy | Los M. | Interne geneeskunde | Multicenter | Nee | Ja |
| CAIRO 7 | Radioembolization with 166Ho-microspheres in elderly and/or fragile patients with previously untreated unresectable liver-only metastases of colorectal cancer, CAIRO7 study of the Dutch Colorectal Cancer Group (DCCG) | Los M. | Interne geneeskunde | Multicenter | Nee | Ja |

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| MajesTEC-7 | A Phase 3 Randomized Study Comparing Teclistamab in Combination with Daratumumab SC and Lenalidomide (Tec-DR) versus Daratumumab SC, Lenalidomide, and Dexamethasone (DRd) in Participants with Newly Diagnosed Multiple Myeloma Who are Either Ineligible or not Intended for Autologous Stem Cell Transplant as Initial Therapy | Nijhof, I.S. | Interne geneeskunde | Multicenter | Nee | Ja |
| EPCORE FL-1 | A Phase 3, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Nijhof, I.S. Combination with Rituximab and Lenalidomide (R2) compared to R2 in Subjects with Relapsed or Refractory Follicular Lymphoma (EPCORE™ FL-1) | | Interne geneeskunde | Multicenter | Nee | Ja |
| M20-621 | A Phase 3, Randomized, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with R-CHOP Compared to R-CHOP in Subjects with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL) | Nijhof, I.S. | interne geneeskunde | Multicenter | Nee | Ja |
| MajesTEC-4 | Phase 3 Study of Teclistamab in Combination with Lenalidomide versus Lenalidomide Alone in Participants with Newly Diagnosed Multiple Myeloma as Maintenance Therapy Following Autologous Stem Cell Transplantation | Nijhof, I.S. | Interne geneeskunde | Multicenter | Nee | Ja |
| K+ in CKD | Renoprotective effecten van kaliumsuppletie bij chronische nierschade | Ocak, G. | Interne geneeskunde | Multicenter | Nee | Ja |
| Resolve Lung | A Randomized, Double-blind, Placebo-controlled Phase 2 Study with open-label Extension to Assess the efficacy and Safety of Namilumab in Subjects with Chronic Pulmonary | Veltkamp, M. | Longziekten | Multicenter | Nee | Ja |
| TETON-2 | A Randomized, Double-blind, Placebo-controlled, Multinational, Phase 3 Study of the Efficacy and Safety of Inhaled Treprostinil in Subjects with Idiopathic Pulmonary Fibrosis | Veltkamp, M. | Longziekten | Multicenter | Nee | Ja |
| IPF Comfort | A DOUBLE-BLIND, RANDOMISED, PLACEBO CONTROLLED, TWO PERIOD CROSS-OVER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ORVEPITANT IN CHRONIC COUGH IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS | Veltkamp, M. | Longziekten | Multicenter | Nee | Ja |
| ATYR1923-C-004 | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Efzofitimod in patients with Pulmonary Sarcoidosis. | Veltkamp, M. | longziekten | Multicenter | Nee | Ja |
| RACCOON | Endobiliary radiofrequency ablation for malignant obstruction due to perihilar cholangiocarcinoma: a randomized controlled trial. | Verdonk, R.C. | MDL (maag-, darm- en leverziekten) | Multicenter | Nee | Ja |
| SAFEST | StAtins in Frail oldEr patients with ischemic Stroke or Transient ischemic attack | Hilkens, P.H.E. | Neurologie | Multicenter | Nee | Ja |
| OCEANIC-STROKE | A multicenter, international, randomized, placebo controlled, double-blind, parallel group and event driven Phase 3 study of the oral FXIa inhibitor asundexian (BAY 243334) for the prevention of ischemic stroke in male and female participants aged 18 years and older after an acute non-cardioembolic ischemic stroke or high-risk TIA | Kerklaan, J. | Neurologie | Multicenter | Nee | Ja |
| ENFORCE | Impact of peri-operative tEstosterone levels oN Functional and oncological Outcomes following RadiCal prostateCtomy (ENFORCE) | Melick van, H.H.E. | Urologie | Multicenter | Nee | Ja |
| E.mbrace | Randomized, Double-blind, Placebo-controlled, Multicenter Phase 3 Study to Assess the Efficacy, Safety And Immunogenicity of Vaccination With ExPEC9V in the Prevention of Invasive Extraintestinal Pathogenic Escherichia coli Disease in Adults Aged 60 Years And Older with a History of Urinary Tract Infection in the Past 2 Years | Selm van, S. | Urologie | Multicenter | Nee | Ja |
| Voorspellende determinanten van kwaliteit van leven | Voorspellende determinanten van kwaliteit van leven bij hart- en vaat patiënten | Balt, J.C. | Cardiologie | Multicenter | Nee | Nee |
| DIAMOND TEMP | DiamondTemp™ Global Registry | Boersma, L.V.A. | Cardiologie | Multicenter | Nee | Nee |

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| NET | Management and outcome of neuroendocrine tumors of the appendix in children; a multicenter historical cohort study | Go, P.M.N.Y.H. | Chirurgie/heelkunde | Multicenter | Nee | Nee |
| | Gebruikersonderzoek naar de ervaringen van patiënten en zorgverleners met het 'Patients like me' dashboard bij de behandeling van borstkanker. | Doeksen, A. | Chirurgie/heelkunde | Multicenter | Nee | Nee |
| PREOPANC-4 | Nationwide implementation program for optimal multidisciplinary management and resection of locally advanced pancreatic cancer (PREOPANC-4) | Santvoort van, H.J. | Heelkunde | Multicenter | Nee | Nee |
| The impact of Health Information Technology on the performance of Dutch hospitals. | The impact of Health Information Technology on the performance of Dutch hospitals. | Bos, W.J.W. | Interne geneeskunde | Monocenter | Nee | Nee |
| Therapietrouw m.b.t de vochtbeperking bij hemodialysepatiënten | De eeuwige strijd van hemodialysepatiënten met hun vochtbeperking | Hendriks-Smidt, S. | Interne geneeskunde | Monocenter | Nee | Nee |
| DePRORA | Determinants of Patient Reported Outcomes in a Dutch Rheumatoid Arthritis population SDB 2022-008 | Jamnitski, A. | Interne geneeskunde | Multicenter | Nee | Nee |
| SOFA score predictiemodel bij COVID-19 IC patienten | SOFA score evaluation over time to predict COVID-19 outcome in time of scarcity in ICU beds; do the most for the most. External validation of the SOFA decision aid model from the Maastricht Intensive Care COVID cohort (MaastrICCht) | Moeniralam, H. | Interne geneeskunde | Multicenter | Nee | Nee |
| TERA | Thrombosis Etiology and Risk Assessment SDB 2022-009 | Söhne, M. | Interne geneeskunde | Multicenter | Nee | Nee |
| ATCAM | Attitudes towards the use children with gastrointestinal parents and pediatricians | Vlieger, A. | Kindergeneeskunde | Multicenter | Nee | Nee |
| Terughoudendheid bij opioïden | Morfine: een benauwd idee? Wat weerhoudt benauwde patiënten in de palliatieve fase om de voorgeschreven opioïden in te nemen? | Ribbert, J.G.M. | Longziekten | Monocenter | Nee | Nee |
| SET-Q Interobserver variability EUS | Interobserver variability in management of subepithelial lesions with endoscopic ultrasonography (EUS) | Verdonk, R.C. | MDL (maag-, darm- en leverziekten) | Multicenter | Nee | Nee |
| SDM-RCC | Een prospectieve studie ter evaluatie van de implementatie van een Samen Beslissen strategie bij afwijkingen van de nier. | Melick van, H.H.E. | Urologie | Multicenter | Nee | Nee |