

Onderzoek goedgekeurd door de RvB in de periode september t/m december 2019 (St. Antonius Ziekenhuis)

Acroniem	Studietitel	Hoofdonderzoeker	Afdeling	Monocenter/ Multicenter	eigen geïnitieerd	WMO plichtig?
AGE-AWARE	Postoperative remote monitoring of vital signs in older cardiac surgery patients	dr. Noordzij, P.G.	Anesthesiologie	Monocenter	Ja	Ja
PACK	Platelet reactivity in patients with Atrial Fibrillation and Coronary Artery Disease under dabigatran, apixaban and VKA	dr. ten Berg, J.M.	Cardiologie	Monocenter	Ja	Ja
Nasal high flow op de verpleegafdeling longziekten	Nasal high flow in patients with exacerbation COPD and/or pneumonia on the lungward	dr. Nienhuis, W.A.	Longziekten	Monocenter	Ja	Ja
Distractie van het duimbasisgewicht: 6 versus 8 weken.	Difference in Patient Reported Outcomes at 1 year after 6 or 8 weeks of carpometacarpal joint distraction: a Randomized Controlled Non-Inferiority Trial. A.B.	dr. Mink van der Molen,	Plastische chirurgie	Monocenter	Ja	Ja
REALITY	Reality- Long-Term real-World Outcomes Study on Patients Implanted with a Neurostimulator	dr. Nijhuis, H.J.A.	Anesthesiologie	Multicenter	Ja	Nee
PREDOMS consult	Fidelity of performing a complex nursing intervention to prepare frail older patients for cardiac surgery (the PREDOMS consult): a multicenter cohort study protocol	Smilde, A.	Cardio-thoracale chirurgie	Multicenter	Ja	Nee
FOCUS	Future of cancer Genetic Testing as usual and standard care-ovarian cancer study	dr. Bokkers, K.	Gynaecologie	Multicenter	Ja	Nee
MINI-CARE	The minimal clinically important difference for decisional conflict, impact of event, body image scale and the Short Form-36 among women with breast cancer (MINI-CARE).	dr. Doeksen, A.	Heelkunde	Monocenter	Ja	Nee
CARE	Decision Aid for Post Mastectomy Breast Reconstruction after Mastectomy: A Randomized Controlled Trial	dr. Doeksen, A.	Heelkunde	Monocenter	Ja	Nee
Buddyhuis	Breast Cancer Buddy House: introducing a new concept.	dr. Doeksen, A.	Heelkunde	Monocenter	Ja	Nee
Kwaliteit van leven na ECLS therapie op de IC	Kwaliteit van leven na ECLS op de IC	Pol. I. van de	IC (intensive care)	Monocenter	Ja	Nee
Patiëntgerichte zorg	Patiëntgerichte zorg. Een probleemanalyse naar de informatiebehoeften en begeleiding van patiënten met een mammacarcinoom tijdens de adjuvante behandeling met antihormonale therapie.	Graat, S.	Interne Geneeskunde verpleegafdeling	Monocenter	Ja	Nee
Capillair versus Veneus	Bepalingen uit capillaire afname versus bepalingen uit veneuze afname	Holten van, T.C.	Klinische chemie	Monocenter	Ja	Nee
Verificatie Trop I POC	Verificatie Trop I POC toepassing m.b.v. een capillaire afname	dr. Bikker, A.	Klinische chemie	Monocenter	Ja	Nee
Influence of CYP2C19 genotype on the efficacy of clopidogrel in the secondary prevention after acute ischemic stroke/transient ischemic attack	Influence of CYP2C19 genotype on the efficacy of clopidogrel in the secondary prevention after acute ischemic stroke/transient ischemic attack	dr. Harmsze, A.	Klinische farmacie	Monocenter	Ja	Nee
Vancomycin Pop-PK in obese using TDM data	Pharmacokinetics of vancomycin in obese patients using routine care TDM data	prof. dr. Knibbe, C.A.J.	Klinische farmacie	Monocenter	Ja	Nee
OAT-FAILURE	Drug-induced sleep endoscopy: retrospective analysis of positive versus negative chinlift maneuver as a prediction tool for failure of oral appliance treatment	dr. Veugen, C.C.A.F.M.	KNO (keel-, neus- en oorheelkunde)	Monocenter	Ja	Nee
bloedafname vs screeningsvragenlijst bij infliximab	Vervolgonderzoek bloedafname vs screeningsvragenlijst bij infliximab	dr. Trapman, L.	Longziekten	Monocenter	Ja	Nee
niet medische interventies om heropname van COPD-patiënten te reduceren	onderzoek naar welke niet-medische interventies geïmplementeerd kunnen worden om de klinische heropnames van patiënten met COPD te reduceren.	Trapman, L.	Longziekten	Monocenter	Ja	Nee

Acroniem	Studietitel	Hoofdonderzoeker	Afdeling	Monocenter/ Multicenter	eigen geïnitieerd	WMO plichtig?
ACID	Acetic acid chromoendoscopy for detection of neoplastic Barret's esophagus	dr. Weusten, B.L.A.M.	MDL (maag-, darm- en leverziekten)	Multicenter	Ja	Nee
S.O.S.MS: development of a standard outcome set for MS	S.O.S.MS: Development of an international standard outcome set for Multiple Sclerosis	Daniels, K.	Neurologie	Monocenter	Ja	Nee
Lemaire bij VKB	Lemaire bij VKB	dr. J.C. Zijl	Orthopedie	Monocenter	Ja	Nee
RIS-CF	RCT naar het effect van een gedragsexperiment op cardiale angst	dr. Vries de, F.A.	Psychiatrie - Medische psychologie	Monocenter	Ja	Nee
Klinimetrische eigenschappen van de BCTQ-DLV	Betrouwbaarheid en validatie van de Nederlandse vertaling van de Boston Carpal Tunnel Questionnaire (BCTQ) bij patiënten met Carpal Tunnel Syndroom (CTS)	Aret-van Dam, J.	Revalidatie	Monocenter	Ja	Nee
CiVS	Circular of spalk, behandeling colles fractuur	dr. D. van der Velde	SEH (Spoedeisende Eerste Hulp)	Monocenter	Ja	Nee
68GA-PSMA-PET/C	Additional value of 68GA-PSMA-PET/CT in patients with suspicion of prostate cancer despite negative MRI	dr. Bergh van den, R.C.N.	urologie	Monocenter	Ja	Nee
veranderingen in cerebral glucose metabolism during anaesthesia	Neurotoxic changes in cerebral glucose metabolism during anaesthesia and major surgery; is the polyol pathway activated?	dr. Scholten. E.	Anesthesiologie	Multicenter	Nee	Ja
ISOCS	Iron status and outcome in cardiac surgery	dr. Noordzij, P.G.	Anesthesiologie	Multicenter	Nee	Ja
ReVEAL iFR	Radiographic imaging Validation and EVAluation for Angio iFR	dr. Kuijk J.P. van	Cardiologie	Multicenter	Nee	Ja
OPTION	Comparison of Anticoagulation with Left Atrial Appendage Closure after AF Ablation	dr. Boersma L.V.A.	Cardiologie	Multicenter	Nee	Ja
AFR-Prophet	Prospective, non-randomized, pilot study to assess safety and efficacy of a novel Atrial Flow Regulator (AFR) in patients with Pulmonary Hypertension	dr. Post M.	Cardiologie	Multicenter	Nee	Ja
POTOMAC	A phase III randomized, open-label, multi-centre, global study of Durvalumab and Bacillus Calmette-Guerin (BCG) administered as combination therapy versus BCG alone in highrisk- BCG-naïve non-muscle-invasive bladder cancer patients	dr. Hunting C.B.	Interne geneeskunde	Multicenter	Nee	Ja
PERFECT	Pragmatic trial baricitinib versus First biological in "Tight Control" Patients suffering from Rheumatoid Arthritis.	dr. Vreugdenhil, S.A.	Interne geneeskunde	Multicenter	Nee	Ja
HOLLANT	Effect of High-volume Online hemodiafiltration on intra-dialytic hemodynamic stability and cardiac function in chronic hemodialysis patients.	prof. dr. Bos, W.J.W.	Interne geneeskunde	Multicenter	Nee	Ja
LEAP	A Phase 3, Randomized, Double-blind Study to Compare the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Lenvatinib (E7080/MK-7902) Versus Pembrolizumab and Placebo as First Line Treatment for locally Advanced or Metastatic Urothelial Carcinoma in Cisplatin-ineligible Participants Whose Tumors Express PD-L1, and in Participants Ineligible for Any Platinum-containing Chemotherapy Regardless of PD-L1 Expression (LEAP-011)	dr. Los, M.	Interne geneeskunde	Multicenter	Nee	Ja
I-ITP	Prospective multicenter cohort for evaluation of changes in Immune profile and platelet function after start of TPO-receptor agonist in patients with chronic ITP	dr. Koene, H.R.	Interne geneeskunde	Multicenter	Nee	Ja
HOVON 156 AML	A phase 3, multicenter, open-label, randomized, study of gilteritinib versus midostaurin in combination with induction and consolidation therapy followed by one-year maintenance in patients with newly diagnosed Acute Myeloid Leukemia (AML) or Myelodysplastic syndromes with excess blasts-2 (MDS-EB2) with FLT3 mutations eligible for intensive chemotherapy	dr. Söhne, M.	Interne geneeskunde	Multicenter	Nee	Ja

Acroniem	Studietitel	Hoofdonderzoeker	Afdeling	Monocenter/ Multicenter	eigen geïnitieerd	WMO plichtig?
LyRICX	Liposomal iRinotecan, Carboplatin or oXaliplatin in the first line treatment of esophagogastric cancer: a randomized phase 2 study	dr. Los, M.	Interne geneeskunde	Multicenter	Nee	Ja
AC-065D301/PHASE	A multicenter, randomized, double-blind, group-sequential, placebo-controlled 52-week period followed by a 104-week, single-arm, open-label period study in participants with sarcoidosis-associated pulmonary hypertension (SAPH) to assess the efficacy and safety of oral selexipag	dr. Mager, J.J.	Longziekten	Multicenter	Nee	Ja
Galliarde	A 52-Week, open-label, single-arm study to evaluate the safety and tolerability of 24-hour daily exposure of continuous subcutaneous infusion of ABBV-951 in subjects with Parkinson's disease	dr. Huisman M.H.B.	Neurologie	Multicenter	Nee	Ja
TREC	Blood transfusion requirements and mortality during extracorporeal membrane oxygenation: a retrospective observational international multi-center study	dr. Scholten, E.	Anesthesiologie	Multicenter	Nee	Nee
POLESTAR	Project to look for early discharge in patients undergoing TAVO with ACURATE- International multi-center early discharge TAVI program	dr. Rensing, B.J.W.M.	Cardiologie	Multicenter	Nee	Nee
FU-IVF	Follow-up of patients with Idiopathic Ventricular Fibrillation	dr. Balt, J.C.	Cardiologie	Multicenter	Nee	Nee
KODEX-EPD PSOT	Patient Specific Optimized Therapy (PSOT) Study	dr. Boersma, L.V.A.	Cardiologie	Multicenter	Nee	Nee
DUTCH-AF	Prospective evaluation of dosing and adherence to anticoagulant treatment and the risk for cardiovascular complications and bleeding in atrial fibrillation	dr. Boersma, L.V.A.	Cardiologie	Multicenter	Nee	Nee
SADI-S	Nutriton status after two-steps single-anastomosis duodenal bypass with sleeve gastrectomy	Nawas Al, M.	Heelkunde	Multicenter	Nee	Nee
G-PEP	An European multi-centre cohort study for unravelling pharmacokinetic and genetic factors underlying post-ERCP pancreatitis	dr. Sperna Weiland, C	Heelkunde	Multicenter	Nee	Nee
DPOG-TDM	Therapeutic drug monitoring of oral anticancer drugs	dr. Los, M.	Interne geneeskunde	Multicenter	Nee	Nee
ProlaC	ProlaC- a multicenter Prolactinoma Cohort	dr. Wakelkamp, I.M.M.J.	Interne geneeskunde	Multicenter	Nee	Nee
Procalcitonine in neonates	Diagnostic additional value of procalcitonine in neonates suspect for sepsis	dr. Heidema, J.	Kindergeneeskunde	Multicenter	Nee	Nee
DISE-OAT	Drug-included sleep endoscopy: positieve versus negative chinlift as a predictor tool for success rate oral appliance treatment	dr. Veugen, C.C.A.F.M.	KNO (keel-, neus- en oorheelkunde)	Multicenter	Nee	Nee
PACIFIC R	First real-world data on unresectable stage III NSCLC patients treated with durvalumab	dr. Kastelijn, E.A.	Longziekten	Multicenter	Nee	Nee
BMI and treatment outcome of carboplatin	The effect of BMI on treatment outcome of carboplatin-based chemotherapy in patients with metastatic non-small cell lung cancer	dr. Schramel, F.M.N.H.	longziekten	Multicenter	Nee	Nee
DPCS	Course and Management of Primary Biliary Cholangitis in the Netherlands-a multicenter nation-wide cohort study	dr.Verdonk, R.C.	MDL (maag-, darm- en leverziekten)	Multicenter	Nee	Nee
Papilla Minor	Clinical outcome after removal or long-term indwelling of plastic stents in patients with endoscopically treated walled-off pancreatic necrosis: a retrospective cohort study	dr. Verdonk, R.C.	MDL (maag-, darm- en leverziekten)	Multicenter	Nee	Nee
PDiv	Clinical outcome of endoscopic therapy in patients with symptomatic pancreas divisum	dr. Verdonk, R.C.	MDL (maag-, darm- en leverziekten)	Multicenter	Nee	Nee
Lordy	Defining loss-of-response to anti-TNF agents in patients with IBD beyond 1 year	dr. Boeckel, van P.	MDL (maag-, darm- en leverziekten)	Multicenter	Nee	Nee
Prospective Registration of endoscopic Full Thickness Resection	Prospective Registration of endoscopic Full Thickness Resection in the Netherlands	prof. dr. Weusten, B.L.A.M.	MDL (maag-, darm- en leverziekten)	Multicenter	Nee	Nee
Oncokompas voor partners	"Efficacy and cost-utility of the eHealth application 'Oncokompas' for partners of patients with incurable cancer."	Verbeek, N.	Oncologie verpleging	Multicenter	Nee	Nee
Roadsaver	Prospective, single-arm, multi-center, observational study to further confirm safety and efficacy of the dual-layer micromesh RoadsaverTM Carotid Stent for the treatment of carotid artery stenosis in patients considered eligible for elective stenting procedure	dr. Heuvel van den, D.A.F.	Radiologie	Multicenter	Nee	Nee

Acroniem	Studietitel	Hoofdonderzoeker	Afdeling	Monocenter/ Multicenter	eigen geïnitieerd	WMO plichtig?
SELECT	Stromal Enhancement on Breast MRI as Biomarker for Survival with Endocrine Therapy	Wolters- van der Ben, E.J.M.	Radiologie	Multicenter	Nee	Nee