Research Opportunities at Park Nicollet

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Area	Study Purpose	Study Treatment	Significant Inclusion Criteria	For More Information	Principal Investigator	Contact
HVC	To evaluate ECG-based measures for predicting cardiac resynchronization therapy (CRT) response by using body-surface ECG and cardiac activation data	Collect data and information on patients who have a Cardiac Resynchronization Therapy Device (CRT-D) for at least 6 months.	Age ≥18 year Implanted with a Medtronic CRT-D device for at least 6 months		Jay Simonson, MD	Jan Walters 952-993-1776
HVC	Comparing effectiveness of atrial ablation vs. rate and or rhythm control drugs for the treatment of atrial fib	Left atrial ablation Standard medical management	Age 18 yrs or > Atrial fib warranting therapy beyond observation Eligible for catheter ablation and >/= 2 rhythm control and / or /= 3 rate control drugs	http://clinicaltrials.gov/ct2/show/NCT00911508?term=CABANA&rank=1	Jay Simonson, MD	Lorene Brown 952-993-3982

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HVC	Demonstrate the safety and effectiveness of the Freezer Xtra Surgical Cardiac CryoAblation Catheter for abnormal fast beating of the heart due to abnormal electrical impulses in the heart	The tip of the cryoblation catheter is cooled to sub-zero temperatures then applied to the tissue inside the heart that is causing the abnormal electrical pulses	Have supraventricular tachycardia (STV) compatible with atrioventricular nodal reentrant tachycardia (AVNRT)	http://clinicaltrials.gov/ct2/show/NCT01426425?term=medtronic+icy&rank=1	Hongsheng Guo, MD	Meaghan Morton 952-993-2066
HVC	Test the hypothesis that canakinumab treatment of patients with MI and elevated hsCRP will prevent recurrent cardiovascular events and patients with MI and pre-diabetes, will prevent new onset diabetes.	Biologic given SQ every 3 months. Dose of 50mg, or 150 mg, or 300 mg or Placebo.	Age ≥18 years Acute or Prior MI > 30 days hsCRP > 2 mg/L	http://clinicaltrials.gov/ct2/show/NCT01327846?term=cantos&rank=1	Andrew Smith. MD	Laura Brady 952-993-2758
HVC	Provide ongoing information on the acute and chronic performance of Medtronic market-release cardiac therapy products	Ongoing source of information on the acute and chronic performance of Medtronic market-released cardiac therapy products	Implanted or intended to be implanted with at least one Medtronic market-released product used for pacing, sensing, or defibrillation. Implanted ≤30 days.	http://clinicaltrials.gov/ct2/show/NCT00911508?term=cabana&rank=1	Jay Simonson, MD	Jan Walters 952-993-1776

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RRC (Rheumatology)	Assess the short term and long term effectiveness of two anti-TNF agents when given in combination with methotrexate	Cimzia + methotrexate (MTX) compare to Humira + MTX for Rheumatoid Arthritis	Age ≥18 Dx RA Positive RF or anti-CCP Swollen ≥4 DAS28 >3.2 CRP ≥10mg/L or ESR ≥ 28 mm/hr Inadequate response to MTX MTX 15-25mg/wk x 8 weeks Corticosteroid ≤ 10mg/day	http://clinicaltrials.gov/ct2/show/NCT01500278?term=ra0077&rank=1	Robert Tierney, MD	Laura Brady 952-993-2758

Area	Study Purpose	Study Treatment	Significant Inclusion Criteria	For More Information	Principal Investigator	Contact
Neurology Stroke/TIA	TIA: Is clopidogrel effective in preventing a major ischemic event after TIA or minor stroke	Clopidogrel 75mg initiated within 12 hours of a TIA compared to ASA	TIA with complete resolution of deficit or minor ischemic stroke with minor residual deficit Able to randomize within 12 hours of symptom onset Head CT or MRI has ruled out hemorrhage or other pathology	Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke (POINT) Trial - Full Text View - ClinicalTrials.gov	Matthew Ostrander, MD	Dianna Martin 952-993-3062

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Diabetes: type 1	*Hylenex* recombinant is a product used to help the body absorb and circulate injectable drugs. Previous clinical studies of insulin given along with *Hylenex* recombinant have shown insulin action times that better mimic the natural insulin response to a meal. The purpose of this study is to evaluate the effectiveness, safety and tolerability of two formulations of *Hylenex* recombinant injected with each infusion set change compared to not injecting *Hylenex* recombinant. One formulation is approved by the United States Food and Drug Administration (FDA) and the other is not yet approved.	Hylenex recombinant vs. none	1. Age 18+ 2. Have an A1C 6.5%-9.5% 3. Have had type 1 diabetes for at least one year 4. Currently using an insulin pump and are willing to potentially switch to a different infusion set and/or tubing. 5. Currently take less than 300 units of rapid-acting insulin a day.	No information is available on the clinicaltrials.gov website at this time.	Glenn Matfin, MD	Penny Thomsen 952-993-5823

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Diabetes: Type 2	Test the safety and effectiveness of a once a week exenatide (Byetta) EQW and compare cardiovascular outcomes in patients with type 2 diabetes that take EQW or a placebo.	Exenatide (Byetta) vs. placebo	1. Age 18+ 2. Have an A1C 6.5%-10% 3. Must have had a cardiovascular event such as heart attack, stroke, stent placement, balloon placement. 4. Do not have to be on diabetes medications 5. OR on oral diabetes medications OR on insulin OR insulin + up to two orals.	For more information about the study, please see: http://clinicaltrials.gov/ct2/show/NCT01144338?term=byetta+vs+placebo&rank=4	Richard Bergenstal, MD	Penny Thomsen 952-993-5823
Diabetes: type 2	To compare the effectiveness of Glimepride, Januvia, Victoza or Lantus in combination with Metformin in maintaining metabolic control (A1C) as well as other benefits and potential side effects.	Metformin in combination of other treatments listed in Study Purpose column	1. Age 30+ at diagnosis and have been on metformin for ≤five years 2. OR Age 20+ at diagnosis and have been on Metformin for ≤five years if Native American 3. Have an A1C 6.8%-8.5%	For more information about the study, please see: http://clinicaltrials.gov/ct2/show/NCT01794143?term=grade&rank=1	Richard Bergenstal, MD	Penny Thomsen 952-993-5823

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Struthers Parkinson's Center	Neuroprotection for Parkinson's disease	Pioglitazone or placebo	Diagnosed with Parkinson's disease within the last 5 years; treatment with rasagiline or selegiline	http://clinicaltrials.gov/ct2/show/NCT01280123?term=parkinson%27s&rank=15	Martha Nance, MD	Kathy Duderstadt, BSN 952-993-5903
Struthers Parkinson's Center	Neuroprotection for Huntington's disease	Creatine or placebo	Early-mid stage Huntington's disease	http://clinicaltrials.gov/ct2/show/NCT00712426?term=crest&rank=6	Martha Nance, MD	Kathy Duderstadt, BSN 952-993-5903
Struthers Parkinson's Center	Neuroprotection for Parkinson's disease	Nicotine patch or placebo	Diagnosed within 18 months of study enrollment	http://clinicaltrials.gov/ct2/show/NCT01560754?term=nic-pd&rank=1	Martha Nance, MD	Kathy Duderstadt, BSN 952-993-5903

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Cancer Type	Study Purpose	Study Treatment	For More Information	Principal Investigator	Contact
Breast Cancer	Study to determine whether vitamin D3 supplements decrease muscle and bone pain for women who take aromatase inhibitors	Randomized study comparing 600 IUs to 4000 IUs vitamin D3	For more information about the study please see: www.clinicaltrials.gov/ct2/results?term=NCT01509079	Alice Shapiro, PhD, RD	Alice Shapiro 952-993-1704
Breast Cancer Prevention	Study to evaluate if green tea extract reduces risk of breast cancer	Randomized study of green tea extract compared to placebo tablets for a one-year period	For more information about the study please see: http://www.clinicaltrials.gov/ct2/show/NCT00917735	Karen Swenson, RN, PhD	Julia Nissen 952-993-3973

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Ovarian Cancer	To evaluate quality of life and toxicity in elderly women who are receiving standard chemotherapy for ovarian or peritoneal cancer	Patients will receive standard chemotherapy for ovarian cancer and will be evaluated for quality of life and treatment toxicity.	For more information about the study, please see: GOG 273 Elderly Ovarian Cancer:	Rachel Lerner, MD	Laura Rockwell, RN 952-993-1737
Ovarian Cancer	To evaluate if counseling patients on a healthy diet and physical activity will improve survival for women who have completed initial treatment for ovarian or peritoneal cancer.	Patients will be randomized to counseling for diet and physical activity vs. general health counseling following completion of treatment for ovarian or peritoneal cancer.	For more information about the study please see: GOG 225 LIVES	Rachel Lerner, MD	Laura Rockwell, RN 952-993-1737
Ovarian Cancer	To evaluate if adding weekly administration of AMG386 vs. placebo for 18 months to standard treatment of carboplatin/paclitaxel improves disease free survival for ovarian or peritoneal cancer	Randomized study comparing weekly infusions of AMG386 vs. placebo in addition to standard treatment of carboplatin and paclitaxel for first line treatment of ovarian or peritoneal cancer.	For more information about the study please see: Amgen GOG 3001 Trinova 3	Rachel Lerner, MD	Laura Rockwell, RN 952-993-1737
Recurrent Ovarian Cancer	To evaluate if adding VTX-2337 is better than liposomal doxorubicin in treating patients with recurrent or persistent ovarian, fallopian tube or primary peritoneal cancer	Randomized study comparing VTX-2337 + liposomal doxorubicin to liposomal doxorubicin alone	For more information about the study please see: VentiRx GOG 3003 Study	Rachel Lerner, MD	Laura Maybon, RN 952-993-5710

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Cancer Type	Study Purpose	Study Treatment	For More Information	Principal Investigator	Contact
Diffuse Large B Cell (DLBC) Lymphoma	To evaluate the safety and effectiveness of a new targeted therapy compared to standard therapy with rituximab for relapsed DLBC lymphoma	Randomized study comparing rituximab + inotuzumab ozogamicin to rituximab + bendamustine or rituximab + gemcitabine	For more information about the study please see: www.clinicaltrials.gov/ct2/results?term=NCT01232556	Rachel Lerner, MD	Elsie Anderson, RN 952-993-6723
Diffuse Large B Cell (DLBC) Lymphoma	To evaluate the safety and effectiveness of GA101 in combination with CHOP chemotherapy in untreated DLBC lymphoma	Randomized study comparing rituximab – CHOP to GA101-CHOP for untreated DLBC lymphoma	For more information about the study please see: www.clinicaltrials.gov/ct2/results?term=NCT01287741	Rachel Lerner, MD	Elsie Anderson, RN 952-993-6723
Lung Cancer	To evaluate the safety and effectiveness of MEDI-575 in combination with standard chemotherapy for patients with standard chemotherapy for squamous cell lung cancer	Randomized study comparing carbo/taxol chemotherapy vs. MEDI-575 + carbo/taxol chemotherapy for patients with previously untreated squamous cell lung cancer	For more information about the study, please see: MedImmune MEDI-575 Lung	Kendra Kubiak, MD	Laura Maybon, RN 952-993-5710

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Prostate Cancer	To compare two different doses of study drug versus docetaxel with prednisone for first line treatment of hormone-refractory prostate cancer (FIRSTANA)	Randomized study of two different doses of cabazitaxel plus prednisone versus docetaxel plus prednisone.	For more information about the study please see: http://www.clinicaltrials.gov/ct2/results?term=NCT01308567	Dylan Zylla, MD	Laura Maybon, RN 952-993-5710
Prostate Cancer	To compare two different doses of study drug with prednisone for metastatic hormone-refractory prostate cancer (PROSELICA)	Randomized study of two different doses of cabazitaxel plus prednisone	For more information about the study please see: SANOFI PROSELICA 11785	Dylan Zylla, MD	Laura Maybon, RN 952-993-5710
Renal Cell Cancer	To evaluate the effectiveness of new oral drug as adjuvant treatment for locally advanced renal cell cancer after surgery	Randomized study comparing pazopanib to placebo as adjuvant treatment for locally advanced renal cancer after surgery.	For more information about the study please see: http://www.clinicaltrials.gov/ct2/results?term=NCT01235962	Kendra Kubiak, MD	Elsie Anderson, RN 952-993-6723
Testicular Cancer	Study to evaluate vascular outcomes for testicular cancer survivors who have received chemotherapy prior to age 30	This study is a one-time cardiovascular assessment performed at the University of Minnesota for men who have had chemotherapy for testicular cancer prior to age 30	For more information about the study please contact Laura Rockwell	Rachel Lerner, MD	Laura Rockwell, RN 952-993-1737

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Additional oncology research studies are available through the Metro Minnesota Community Clinical Oncology Program (MMCCOP). MMCCOP is a non-profit research program sponsored by the National Cancer Institute and participating community hospitals and clinics. Park Nicollet Health Services is a member of this consortium. This program provides people access to the newest therapies available for cancer treatment and prevention and symptom management. Visit ***www.ccopnet.com*** or call 952-993-1517 for more information.