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Clinical Trials

Clinical trials are designed to help provide the answers to some of medicine's most difficult questions. It is through clinical trials, both initiated at NorthShore or done in collaboration with other leading-edge institutions, that we are able to better diagnose, treat and prevent diseases and other health conditions.

NorthShore currently offers a robust list of clinical trials across multiple disciplines—oncology, neurological care, orthopaedics, cardiovascular conditions and many more. Along with these trials, NorthShore is also participating in various clinical trials that have a specific focus on personalized medicine.

We expect that as the field of personalized medicine continues to develop and advance, our participation in additional trials will as well. Some of the clinical trials we are currently recruiting patients for include:

Breast Cancer | Breast / Ovarian Cancer | Cardiovascular Conditions | Endocrinology (Diabetes) | Neurological Care | Prostate Cancer | Head and Neck Cancer

Breast Cancer

Susceptibility Gene Identification in Families with a Genetic Predisposition To Breast Cancer (The SIFT Study)
Aims: Individuals with a hereditary breast cancer syndrome whose causative gene is yet undiscovered must be clinically managed according to the familial cancer pattern. For such families, it is not currently possible to separate those relatives who are at increased risk and those who face average cancer risks. Thus, many individuals with hereditary cancer patterns of unknown etiology will undergo high-risk surveillance and preventative surgery which would not be warranted if their "true" genetic status could be discerned. Once the responsible gene mutation is known, it is possible to change the risk status for family members and provide more individualized management recommendations.
Diagnosis: Men and women who have a personal and/or family history of breast cancer who have a negative genetic test result
Principal Investigator: Peter J. Hulick, MD, MMSc
IRB Approval Number: EH09-008
Sponsor: NorthShore University HealthSystem
Contact: Interested patients should call **847.570.1029**
Open to Enrollment: Yes

AbbVie M12-914: A Phase 3 Randomized, Placebo-Controlled Trial of Carboplatin and Paclitaxel With or Without the PARP Inhibitor Veliparib (ABT-888) in HER2-Negative Metastatic or Locally Advanced Unresectable BRCA-Associated Breast Cancer

Aims: The main purpose of the study is to determine if veliparib in combination with carboplatin and paclitaxel improves the efficacy of chemotherapy alone in participants with a BRCA1 or BRCA2 mutation and HER2-negative metastatic or locally advanced breast cancer. Carboplatin and paclitaxel are chemotherapy drugs are widely used as a treatment for advanced or metastatic (spread to/from other areas) breast cancer.
Diagnosis: Breast Cancer
Principal Investigator: Douglas Merkel, MD
IRB Approval Number: EH14-199
Sponsor: AbbVie
Contact: Interested patients should contact research nurse Michele Britto, RN at **847.570.2109**
Open to Enrollment: Yes

A011106: ALTernate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study

Aims: The purpse of this study is to determine whether neoadjuvant endocrine therapy with fulvestrant or the combination of anastrozole and fulvestrant, is better than anastrozole when given before surgery to shrink the cancer and stop it from growing. Anastrozole inhibits tumor growth by reducing the levels of estrogen and has been approved by the Food and Drug Administration (FDA) of the United States for use after surgery for postmenopausal women with estrogen receptor positive breast cancer.
Diagnosis: Breast Cancer
Principal Investigator: Douglas Merkel, MD
IRB Approval Number: EH14-308
Sponsor: Alliance for Clinical Trials in Oncology
Contact: Interested patients should contact research nurse Michele Britto, RN at **847.570.2109**
Open to Enrollment: Yes

NSABP B-55/BIG 6-13: A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olparib Versus Placebo as Adjuvant Treatement in patients with Germline BRAC1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definiteive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

Aims: The purpse of this study is to compare the addition of olaparib after the usual care of chemotherapy, surgery, and radiation for your type of cancer. In this study, you will get either olaparib or placebo.
Diagnosis: BreastGermline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer
Principal Investigator: Douglas Merkel, MD
IRB Approval Number: EH14-400
Sponsor: NSABP
Contact: Interested patients should contact research nurse Michele Britto, RN at **847.570.2109**
Open to Enrollment: Yes

TNBC: Avatar: Feasibility/Pilot Study of Genomics-Guided Therapeutic Drug Selection for Triple Negative Breast Cancer (TNBC) Using a Patient-Derived Mouse Xenograft

Aims: The purpose of this study is to see if tumor genetics, PDX mouse model and cell lines can be helpful in predictions which treatment would be most

effective for an individual breast cancer pateint. In addition, if your cancer returns, doctors may be able to use their information learned from treating the PDX mouse to guide the choice of treatment for your cancer.
Diagnosis: Triple negative breast cancer
Principal Investigator: Douglas Merkel, MD
IRB Approval Number: EH15-066
Sponsor: The Jackson Laboratory
Contact: Interested patients should contact research nurse Michele Britto, RN at **847.570.2109**
Open to Enrollment: Yes

Breast / Ovarian Cancer

The PROSE Study of BRCA1 and BRCA2 Mutation Carriers
Aims: Women who carry mutations in the BRCA1 or BRCA2 genes are at an increased risk of developing breast and ovarian cancer at some point during their life. However, some mutation carriers develop cancer while others do not. The age of onset of cancer varies among different women who carry BRCA1/2 mutations as well. The purpose of this study is to shed light on the factors which increase the chances of cancer development in BRCA1/2 carriers and to learn which factors are protective. The overall study goal is to identify genes involved in DNA damage recognition and repair pathways that influence BRCA1/2-associated cancer risk. The NorthShore Center for Medical Genetics is collaborating with the University of Pennsylvania and the University of California Irvine, as well as other sites both nationally and internationally in this study.
Diagnosis: Women who have tested positive for a mutation in either the BRCA1 or BRCA2 genes
Principal Investigator: Peter J. Hulick, MD, MMSc
IRB Approval Number: EH05-340
Sponsor: The University of Pennsylvania
Contact: Interested patients should call **847.570.1029**
Open to Enrollment: Yes

Evidence-based Network for the Interpretation of Germline Mutant Alleles (ENIGMA)
Aims: Individuals who undergo genetic testing for BRCA1 or BRCA2 mutations do so in order to know if they or their family members are at higher risk for developing certain cancers. If they are found to carry a mutation, they can enhance screening or pursue preventive surgeries to reduce their risks of developing cancers. About 2-3% of patients who have genetic testing for BRCA1 or BRCA2 receive a result considered a "variant of uncertain significance (VUS)" but this rate can be much higher for genes more recently linked to cancer risk since we are learning more about what is "normal" human variation in these genes. In this instance, patients cannot be certain whether they are at higher risk for developing cancer or not and clinicians have difficulty providing management recommendations. The majority of VUS are rare and population specific, making it complicated at a local level to make determinations on any particular VUS. The ENIGMA consortium was created to pool international data on VUS in an effort to classify them either deleterious or non-pathogenic. This effort originally began with BRCA1 and BRCA2 but has expanded to other inherited cancer risk genes. Participating centers have the option of sending family history data, DNA, and/or tissue samples. The Center of Medical Genetics has committed to sending de-identified information to collaborators of ENIGMA for inclusion in their data analysis. We will not be contributing DNA or tissue samples.
Diagnosis: Men and women who have a personal and/or family history of cancer and have a variant of uncertain significance.
Principal Investigator: Peter Hulick, MD, MMSc
IRB Approval Number: EH12-239
Sponsor: NorthShore University HealthSystem in collaboration with many national and international institutions
Contact: Interested patients should contact, the Center for Medical Genetics at **847.570.1029**.
Open to Enrollment: Yes

Prostate Cancer

Prostate Cancer Medically Optimized Genome-Enhanced Therapy (PROMOTE)*
Aims: This study will include patients with castrate resistant prostate cancer with metastasis who are initiating treatment with abiraterone acetate (AA). This study is currently open only at Mayo Clinic in Rochester, MN. Prior to beginning treatment with AA, patients will go to Mayo Clinic and will undergo a biopsy of a metastatic tumor and have blood drawn. Comprehensive genetic testing will be done on the tumor tissue and blood, including germline and tumor whole genome sequencing as well as implantation of tumor into nude mice. After 12 weeks of treatment with AA, a second biopsy of a metastatic tumor will be done at Mayo Clinic and a similar analysis will be done. Patients will be monitored closely at NorthShore for response to the treatment and changes in therapy will be done as deemed appropriate. Correlation between genetic features and response to AA treatment will be made and genetic data may be used to inform future treatments. Travel and lodging expenses will be covered and a 3 month supply of AA will be supplied by Mayo Clinic.
Diagnosis: Castrate resistant prostate cancer
Principal Investigator: Manish Kohli, MD
Sponsor: Mayo Clinic
Contact: Manish Kohli, MD, kohli.manish@mayo.edu; **507.284.3903**
Open to enrollment: Yes

** This study is being done in collaboration with Mayo Clinic. Suitable patients will be referred to Mayo Clinic and jointly managed by NorthShore physician Daniel Shevrin, MD.*

Identification of Men with a genetic predisposition to ProstAte Cancer: Targeted Screening in BRCA1/2 mutation carriers and controls (The IMPACT Study)
Aims: Men who carry inherited mutations in the BRCA1 or BRCA2 genes are at increased risk of developing prostate cancer. A blood test measuring Prostate Specific Antigen (PSA) is currently the best method to screen for prostate cancer in the general population. However, the effectiveness of using PSA for screening in the BRCA1 and BRCA2 high-risk population is unknown. The overall study goal is to determine the usefulness of available screening methods in men at high risk and to determine new and more effective ways of screening for prostate cancer. Furthermore, we hope to gain a better understanding of the biological process of prostate cancer in BRCA1 and BRCA2 mutation carriers.

The NorthShore Center for Medical Genetics is collaborating with the Institute of Cancer Research and Royal Marsden Hospital NHS Foundation Trust in the United Kingdom as well as other sites both nationally and internationally. The IMPACT study is one of the research initiatives of the NorthShore Center for Prostate Health.

The goal of the international study is to enroll 500 men with BRCA1 mutations, 350 men with BRCA2 mutations and an additional 850 men who have tested negative for known BRCA1 or BRCA2 familial mutations. At NorthShore University HealthSystem, we seek to enroll and study 100 participants.
Diagnosis: Men aged 40 to 69 years who have a known BRCA1 or BRCA2 mutation in their family.
Principal Investigator: Peter Hulick, MD, MMSc
IRB Approval Number: EH08-063
Sponsor: Mr. & Mrs. Jack and Judy Baker, CCRP award
Contact: Interested patients should contact the Center for Medical Genetics at **847.570.1029**.
Open to Enrollment: Yes

Head and Neck Cancer

Head and Neck Cancer

AstraZeneca D4193C0001: A Phase II, Multi-Center, Single-Arm, Global Study of MEDI4736 Monotherapy in Patients with Recurrent or Metastatic Squamous Cell carcinoma of the Head and Neck (SCCHN)
Aims: This study is being carried out to see if an experimental anti-cancer drug called MEDI4736 (study drug) is effective in treating the type of cancer that you have. MEDI4836 is an antibody that has been made in the laboratory that may boost the ability of the immune system to detect and fight cancer.
Principal Investigator: Bruce Brockstein, MD
IRB Approval Number: EH14-364
Sponsor: AstraZeneca
Contact: Interested patients should contact research nurse Elita Fine, RN at **847.570.2698**
Open to Enrollment: Yes

NorthShore Pancreatic Cancer Family Registry
Aims: The primary aim of the research study is to establish a Pancreatic Cancer Family Registry (PCFR) at NorthShore that will serve as a resource pool for future research into the molecular and biological bases of pancreatic cancer susceptibility. The PCFR will act as a repository for socio-demographic, dietary, environmental, clinical and family history data collected from individuals and interested family members with a personal and/or family history of pancreatic cancer.
Diagnosis: Adults who have a personal history of pancreatic cancer, individuals who are members of a family with 1 or more individuals with pancreatic cancer; and/or individuals who have been identified by clinical DNA testing as genetically predisposed to pancreatic cancer (e.g. p16 or BRCA2 mutation carriers)
Principal Investigator: Peter Hulick, MD, MMSc
IRB Approval Number: EH02-334
Sponsor: NorthShore University HealthSystem
Contact: Interested patients should contactthe Center for Medical Genetics at **847.570.1029**.
Open to Enrollment: Yes

Neurological Care

A Phase 1 Study Evaluating the Safety and Pharmacokinetics of ABT-414 in Combination with Radiation Plus Temozolomide or Temozolomide Alone for Subjects with Glioblastoma Multiforme
Aims: The purpose of this study is to determine how the drug ABT-414 works in the body and evaluate its safety in patients with newly diagnosed or recurrent glioblastoma
Principal Investigator: Ryan T. Merrell, MD
IRB Approval Number: EH13-332
Funding Source: AbbVie
Contact: Please call **847.570.2025** with questions regarding the study.
Open to Enrollment: Yes

A071102: A Phase II/III Randomized Trial Of Veliparib Or Placebo In Combination With Adjuvant Temozolomide In Newly Diagnosed Glioblastoma With MGMT Promoter Hypermethylation
Aims: The purpose of this study is to compare the effects, good or bad of the usual treatment (temozolomide) with or without the addition of the investigational drug veliparib for people whose brain tumors show a change in a small region of DNA (gene) called O6-methylguanine methyltransferase (MGMT).
Principal Investigator: Ryan Merrell, MD
IRB Approval Number: EH15-186
Funding Source: Alliance for Clinical Trials in Oncology/AbbVie
Contact: Please call **847.570.2025** with questions regarding the study.
Open to Enrollment: Yes

Cardiovascular Conditions

Tailored Antiplatelet Initiation to Lessen Outcomes due to Decreased Clopidogrel Response after Percutaneous Coronary Intervention (TAILOR-PCI)
Aims: This study is looking for participants who underwent a Percutaneous coronary intervention (PCI) procedure initially presenting with either acute coronary syndrome or stable coronary artery disease. The patients will be randomized to one of two groups (with 50:50 chance): the conventional therapy group in which the patients will receive clopidogrel (Plavix) once daily with retrospective genotype analysis performed at the end of one year of treatment; and the prospective genotyping group, in which the patients will have prospective genotyping performed (via a buccal swab) to guide anti-platelet therapy. Patients in this group who are identified to have reduced function *CYP2C19* allele will receive ticagrelor (Brilinta) twice daily and patients with wild type *CYP2C19* allele will receive clopidogrel (Plavix) once daily. The participants from both groups will have their genotype tested after one year from a stored blood sample drawn while at the hospital.
The purpose of this study is by using pharmacogenomics (perspective and retrospective genotyping) to determine whether choosing medication (antiplatelet therapy) based on an individual genotype will lead to better outcomes defined as a decrease in major cardiac events in patients undergoing PCI.
Participation in the study will last for 12 months with 3 follow up phone visits. The study is expected to be completed in 2016.
Diagnosis: Percutaneous coronary intervention (PCI) procedure
Principal Investigator/s: Jorge Saucedo, MD (NorthShore University HealthSystem); Naveen Pereira, MD (Mayo Clinic)
Sponsor: Mayo Clinic; Spartan Bioscience, Inc. is providing lab equipment for use in this study
Contact: Elena Genova, PhD, **847.444.5314**; egenova-peeva@northshore.org and Jean Skelskey, RN, **847.570.1810**; jskelskey@northshore.org
Open to Enrollment: Yes

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