



Alliance A211701: A Prospective Study to Establish a New Onset Diabetes (NOD) Cohort

Suresh Chari, MD and Srilatha Hosur, MD

Mayo Clinic and Geisinger Wyoming Valley / Henry Cancer Center

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Among the most compelling needs for pancreatic ductal adenocarcinoma (PDAC) today is a rational, evidence-based strategy to detect the cancer at an early stage when it is still resectable and potentially curable. Over 90% of PDAC is sporadic and 85% of sporadic PDAC present at an advanced stage, rapidly progressing to death; only 8.8% are confined to the pancreas [1]. The 5-year survival rate for early, localized PDAC is >10 fold higher than that for PDAC with distant metastases (23.8% vs 2.3%) [1]. Principal challenges to developing an early detection program for sporadic PDAC are the lack of an identified high risk group (HRG) for sporadic PDAC; limited availability of high quality biospecimens; a dearth of biomarkers of early PDAC; and the inability of conventional imaging and absence of novel imaging techniques to identify early PDAC. [1]

There is tremendous optimism for breakthrough innovation in this field. Recent studies provide substantial foundation for a strategic collaborative effort. A high-risk group (HRG) for sporadic PDAC has been identified in subjects over age 50 years who newly develop (DM)[2]. They have a 6-8 fold higher risk of being diagnosed with PDAC within 3 years of meeting criteria for DM [3]. The NCI has acknowledged that studying the relationship between DM and PDAC is one of the highest research priorities in PDAC [8].

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Primary

To prospectively assemble a cohort of subjects >50 and ≤85 years of age with new-onset diabetes (NOD), called the NOD Cohort, in order to:

- estimate the probability of pancreatic ductal adenocarcinoma (PDAC) in the NOD Cohort,
- establish a biobank of clinically annotated biospecimens including a reference set of biospecimens from pre-symptomatic PDAC and control new-onset type 2 diabetes mellitus (DM) subjects,
- facilitate validation of emerging tests for identifying NOD subjects at high risk for having PDAC using the reference set and
- provide a platform for development of an interventional protocol for early detection of sporadic PDAC NOD subjects

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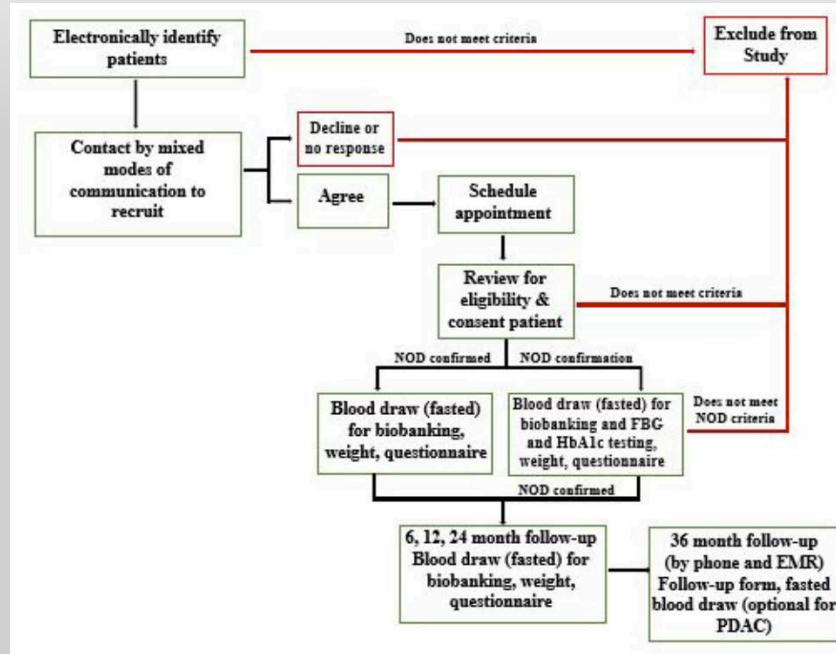
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NOD Study Flow Chart

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Assemble the NOD Cohort (*see flow chart*)

A prospective NOD Cohort of 10,000 enrolled, eligible subjects will be assembled over the next 3 years, with each patient participating for up to 3 years from the date they meet criteria for diabetes. The NCTN/NCORP sites electronic medical record databases or other avenues for recruitment, such as physician and self-referral, will be utilized to identify subjects meeting criteria for NOD

Develop a Biobank

We will follow standardized protocols for collection of data and bio-specimen samples; increase access to data and sharing of data; improve quantity, quality, and continuum of all patient data and bio-specimens; and enhance recruitment processes for study enrollment. All subjects in the NOD protocol will provide biospecimens at baseline (at the time of recruitment), and subsequently at 6, 12, and 24 months. Blood will be collected and kept for storage and future use. The approach is outlined in flow chart.

Estimate the Probability of PDAC in the Prospectively Assembled NOD Cohort

The 1-year, 2-year, and 3-year incidence rates of PDAC and their 95% confidence intervals will be calculated via passive surveillance of health status of all enrolled patients (See Section 7.2).

Establish a Specimen Reference Set to Validate Emerging Tests for Identifying NOD Patients at High Risk for Having PDAC

Future promising biomarkers for PDAC early detection, after the consortium review and approval, can be evaluated on this specimen reference set for its sensitivity, specificity, PPV, and NPV in predicting 1-year, 2-year, and 3-year PDAC risk. The intended clinical application is to identify high risk of NOD patients for PDAC diagnostic work up.

Provide a Platform for Development of an Interventional Protocol for Early Detection of Sporadic PDAC

While this protocol is a minimal-risk study, if efforts to develop predictive models or biomarkers of PDAC in NOD subjects are successful, separate IRB submissions would be made to test screening protocols for PDAC in subjects in this NOD cohort.



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The inclusion criteria are criteria for an invitation to the study (pre-screening/screening). Once consented, verification of NOD status is required for subsequent serial-bio sampling for patients not meeting the criteria of NOD a prior.

Inclusion Criteria

Category	Inclusion Criteria
Consent	<ol style="list-style-type: none"> Willing to provide informed consent and sign an informed consent form. Must sign an authorization for the release of their protected health information.
Age	Candidates must be ≥ 50 and ≤ 85 years of age
Diabetes Mellitus related	<ol style="list-style-type: none"> Must have at least (1) Parameter of Diabetes Mellitus in the past 90 days: <ul style="list-style-type: none"> ◦ Fasting Blood Glucose (FBG) ≥ 126 mg/dl ◦ Hemoglobin A1C(HbA1c) $\geq 6.5\%$ ◦ Random Blood Glucose (RBG) ≥ 200 mg/dl ◦ 2h Post Glucose (PG) ≥ 200mg (11.1 mmol/L) during OGTT (oral glucose tolerance test) <p><i>*Only the aforementioned glycemic parameters measured in outpatient setting are to be included.*</i></p> <ol style="list-style-type: none"> Must have had glycemic parameters measured in the 3-18 months prior to screening without meeting criteria for DM Must not be on anti-DM medications prior to meeting study entry criteria
Biospecimen	<ol style="list-style-type: none"> Patient must be willing to provide blood samples (fasted) at baseline For subsequent serial bio-sampling, patient must meet criteria for NOD (New onset diabetes) (see Table 1 in Section 3.2) and be willing to provide blood samples (fasted) at 6, 12, and 24 months post-enrollment
Questionnaire	Subjects or authorized representative must be willing to complete a detailed questionnaire in English
Chronic severe illness	In physician's judgement, patient's co-morbidities do not limit patient's participation in study interventions (blood draws and questionnaire)

Exclusion Criteria

Category	Exclusion Criteria
Diabetes Mellitus (DM) related	<ol style="list-style-type: none"> Patient met criteria for DM >90 days prior to enrollment, carried a physician diagnosis of DM or used anti-DM medications in the 3-18 months prior to enrollment Has had no glycemic parameter measured within 3-18 months prior to enrollment
Personal history of cancer	<ol style="list-style-type: none"> Patients must not be on active treatment for cancer, carry a current diagnosis of any cancer, and/or be investigated for suspicion of recurrence of past cancer (except non-melanoma skin cancer or carcinoma in-situ of the cervix) Any past history of pancreatic cancer
Steroid use	<ol style="list-style-type: none"> Current chronic or acute oral steroids Recent (within 1 week) intra-articular steroid injection <p><i>Allowed: Nasal, topical steroids, oral budesonide, ophthalmic</i></p>
Acute illness at blood draw	Blood sugar measured in stressful situations such as urgent care, emergency room, or as inpatient
Chronic severe illness	Patients must not have any significant medical illnesses that in the investigator's opinion cannot be adequately controlled with appropriate therapy or would compromise the patient's ability to tolerate study interventions.



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