**RETROSPECTIVE CHART/RECORD REVIEW**

**PROTOCOL TEMPLATE**

*(HRP-503c)*

**STUDY INFORMATION**

* 1. **Title of Project: Incidence, management and outcomes of acute myocardial infarction among young adults.**
  2. **Principal Investigator:** 
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**1.0 Research Introduction**

**1.1 Purpose/Specific Aims**

The purpose of this study is to determine the occurrence, management and outcomes of hospitalized acute myocardial infarction among patients aged 18 to 35 years old (y.o.) from 1/1/1986 to 12/31/2018 in New Jersey.

**Objectives**

* To determine the incidence, management, and outcomes of hospitalized acute myocardial infarction among patients 18 to 35 y.o.
* To explore the differences in the incidence, management, and outcomes of hospitalized acute myocardial infarction patients aged 18 to 35 y.o. compared to older patients aged 65 to 74 y.o. in New Jersey.
* To compare the rate and outcomes of invasive diagnostic and interventional procedures among hospitalized acute myocardial infarction patients 18 to 35 y.o. with those aged 65 to 74 y.o. in New Jersey.

**Hypotheses / Research Question(s)**

* Hypothesis 1: Among patients hospitalized acute myocardial infarction aged 18 to 35 y.o the incidence is low, the management includes more interventional procedures, and the outcomes are better.
* Hypothesis 2: The risk profile among hospitalized acute myocardial infarction patients aged 18 to 35y.o. includes less emphasis on traditional risk factors (age, hypertension, diabetes) and more emphasis on hyperlipidemia compared to older myocardial infarction patients aged 65 to 74 y.o. in New Jersey.
* Hypothesis 3: There may be differences in the outcomes invasive diagnostic and interventional procedures in hospitalized acute myocardial infarction patients aged 18 to 35 y.o. compared to older patients aged 65 to 74 y.o. in New Jersey.

**2.0 Research Significance *(Briefly describe the following in 500 words or less):***

Coronary heart disease (CHD) remains the principal cause of death in the industrialized world1. Despite a series of superb developments in the study and treatment of CHD2 over the past years little there is to know about studies focusing at myocardial infarction in populations under 35 years of age. The incidence of acute coronary syndrome is between 3% and 10% in patients <45 years of age2 but acute myocardial infarction (AMI) is very rare and comprises less than 1% of all AMIs in patients equal or younger than 35 years of age3. Although the number of AMI in this age group plateaued over the past decade4 the incidence CHD is projected to increase5 due to the rising prevalence of risk factors such as smoking and diabetes among these patients6,7. In addition to the burden of the disease itself one must consider the effects of an AMI with regards to the socioeconomic adverse consequences that such an event poses at a young age. A “premature” AMI might affect a person’s ability to work, decrease a family’s income, limit an active lifestyle and establish a longstanding period of disability. In addition, the residual life expectancy of individuals under 35 is higher than older people, an important consideration for those whose infarction may be fatal. Thus far, available data were derived from studies with limited number of patients, short duration of follow-up, not deriving from population data sets and with a higher age cut off, such as 40-55 years old8-10.

The aim of this work is to better characterize in terms of incidence, risk profile, management and outcomes a population who sustained an AMI equal or under 35 years of age between 1985 and 2018 using the Myocardial Infarction Data Acquisition System (MIDAS), a database of all hospitalizations in New Jersey11-14.

The Myocardial Infarction Data Acquisition System (MIDAS) includes all the information needed for this study, has been used in previous studies and has been validated15-20.

**2.1 Research Design and Methods**

This study will be conducted utilizing a limited database of the MIDAS (Myocardial Data Acquisition System) DR (data repository) (IRB# [Pro2013003225](http://eirb.umdnj.edu/eirb/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b1B38EE38A2720F40B24FE4257F082701%5d%5d) – Honest Broker) from years 1/1/1986 through 12/31/2018.

All data from this study will be obtained from the MIDAS DR created by the honest broker. The data to be utilized is detailed in section 4.1. While limited PHI is included in this dataset (namely dates and zip codes), there are minimal risks of disclosure of PHI associated with participation in MIDAS DR. The Cardiovascular Institute has taken precautions to prevent misuse of data by using electronic and physical security systems that protect the privacy of subjects.

**2.2 Date Range For Record Review**

The study will include data from non-Federal hospitals in the State of New Jersey from 1/1/1986 through 12/31/2018. The study will take approximately 2 years to complete.

**2.3****Sample Size**

The Honest Broker will create dataset. There are approximately 4000 patients who were hospitalized for acute myocardial infarction for the years for this present study in New Jersey. This will provide enough statistical power to examine the hypotheses. This number exceeds by far the number included in any of the prior published studies.

**2.4 Record Selection**

All men and women, aged 18 and older, who are part of the MIDAS DR database (this is a database created by the Honest Broker) will be used. Children will not be included because cardiovascular disease is uncommon.

* + 1. **Inclusion Criteria**
* Men and women
* Aged 18 to 74. This includes both the records of the study group and the controls.
  + 1. **Exclusion Criteria**
* Less than 18 years old

**3.0 Study Variables*.***

**3.1 Independent and Dependent Variables or Interventions**

**MIDAS-DR Variables:**

ADMDAT – Admission Date

DSCHDAT – Discharge Date

PATBDTE – Date of Birth

PRDTE1- PRDTE8 – Procedure Dates

ZIP – Zip Code

CAUSE – Cause of death

DEATHRNUM – NJ Death Certificate Number

DRG – Diagnosis-related Group

DSHYR – Discharge Year

DX1-DX9 - Diagnoses

HISPAN – Hispanic ethnicity

HOSP – Hospital Number

LOCATION – Location upon leaving hospital

NEWDTD – Date of death

PATIENT\_ID – Patient ID – Randomly generated MIDAS DR specific unique identifier

assigned to each de-identified patient

PRIME – Primary Insurance

PROC1-PROC8 – Procedure Codes

RACE – Race of Patient

RECDID – Record ID – Randomly generated MIDAS DR specific unique identifier assigned to each admission record in the data repository

SECOND – Secondary Insurance

SEX - Gender

SOURCE – Location before entering hospital

STATUS – Status upon discharge

THIRD – Tertiary Insurance

TOTBIL – Total Billing Amount

**4.0 Project Management**

**4.1 Research Staff and Qualifications**

The Principal investigator (PI), co-investigators, study staff all have completed CITI training. The PI has over 40 years of research experience, and most co-investigators have over 25 years each of research experience and have published papers in peer-reviewed journals.

**4.2 Research Sites**

The research will be conducted at the Cardiovascular Institute, Clinical Academic Building, 125 Paterson Street, Suite 4180, New Brunswick, NJ 08901.

**4.3 Non-Rutgers Site Research**

N/A

**5.0 Research Data Source/s**

**5.1 Secondary Data - Chart Review Process**

N/A – the data used will be created by the Honest Broker see 5.2

**5.2 Data Abstraction**

The Honest Broker will create dataset based on inclusion/exclusion criteria.

**5.3 Data Source**

MIDAS DR (Data Repository) Cardiovascular Institute, Clinical Academic Building, 125 Paterson Street, Suite 4180, New Brunswick, NJ 08901. The data is obtained annually from the NJ Department of Health.

**5.5 Data Management Services**

N/A – no data management services utilized.

**5.6 Data Collection Form (Variables To Be Analyzed):**

See Data collection form as a separate attachment.

**6.0 Waiver or Alteration of Consent Process**

We have requested a waiver of consent and HIPAA. We would be unable to conduct the research without waiver of consent. The study is a retrospective record review. The risks are minimized by using an Honest Broker, limiting access to the dataset to IRB approved personnel. The research is equitable – we use all patients. The study has a favorable risk-benefit ratio.

**6.1 Risks to Subjects**

**A. Description of Subject Risks**

This is a minimal risk study using data from the MIDAS DR created by the Honest Broker. The risk of loss of confidentiality is low. The access to the dataset is limited to the investigators approved by the IRB, using institution computers with password protection. In addition, there are physical barriers in place. The area is locked and controlled by ID card to gain access.

* + - * **Certificate of Confidentiality**

N/A

* + - * **Potential for Benefit**

No direct benefit to the individual patient. However, new knowledge may be useful in the future.

* + - * **Provisions to Protect the Privacy Interests of Subjects**

The access to the dataset is limited to the investigators approved by the IRB, using institution computers with password protection.

**6.2 Secondary Use of the Data**

There are no plans to share the data with other researchers (with or without identifiers) for secondary research.

**7.0 Special Considerations**

**7.1 Health Insurance Portability and Accountability Act (HIPAA)**

We will not be disclosing individually identifiable health information.

**A. Waiver or Alteration of HIPAA Authorization**

Waiver of HIPAA has been requested. We would not be able to do this study without a HIPAA waiver. This is a minimal risk study that could not be done without the waiver. We are not using anything that is not minimally required data to conduct the study and the identifiers will be destroyed at the completion of the data collection.

**7.2 Family Educational Rights and Privacy Act (FERPA)**

N/A

**8.0 Research Data Protection and Reporting**

**8.1 Data Management**

The Honest Broker is responsible for receiving the data. Identifiers (dates) are needed in order to calculate the outcomes time to readmission, cardiovascular death and all-cause death.

Analyses will be done using “R” and SAS® (SAS Corporation, Cary, NC, USA) software. Differences between groups will be examined by univariate and multivariate analyses. The hypothesis will be tested by analyzing rates of events throughout the State by multiple logistic regression adjusting for demographics and comorbidities. Subsequent events will be studied by Kaplan-Meier plots and Cox regression. Risk adjustment will be used to identify matched pairs and adjust for inequalities in severity where appropriate. Data for the differences in incidence, rate of interventional procedures, and outcomes (including readmission and time to readmission, cardiovascular death and all-cause death at 30 days and one-year) will be estimated across racial/ethnicity groups, using Poisson regression with the GENMOD procedure in SAS. MIDAS has been validated in the past for accuracy of the data.

The data will be stored in computers in the offices of the MIDAS personnel in New Brunswick at the Cardiovascular Institute Located at 125 Paterson Street, Suite 4180, New Brunswick, NJ 08901. The links will be destroyed once the data set is established and verified.  The dataset will be destroyed once the data analyses are completed.

Only IRB approved personnel will have access to the limited dataset for this study that is on a password protected computer that is in a locked room with access limited to holders of ID cards who are authorized to access the data.

**8.2 Data Security**

The MIDAS DR data reside in computer files on the Rutgers RWJA HP computer in Piscataway. The offices of the MIDAS personnel are in New Brunswick in the Cardiovascular Institute Located at 125 Paterson Street, Suite 4180, New Brunswick, NJ 08901.

**A. Destruction of Identifiers**

Dataset, including identifiers, will be destroyed at the completion of the study.

**8.3 Reporting Results**

* + 1. **Sharing of Results with Subjects**

N/A

* + 1. **Individual Results**

N/A

* + 1. **Aggregate Results**

N/A

* + 1. **Professional Reporting**

We plan to present the results at state, national, international cardiology meetings, and publication in peer-reviewed journals.

**9.0 Other Approvals/Authorizations**

Cardiovascular Scientific Review board approval has been obtained for this study, and has been provided in the IRB application.

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