Acute Kidney Injury Neutrophil Gelatinase-Associated Lipcalin (N-GAL) Evaluation of Symptomatic Heart Failure Study (AKINESIS)

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AKINESIS is a multi-center prospective, uncontrolled clinical study to assess the utility of a plasma NGAL test (Triage® NGAL Test) and a urinary NGAL test (ARCHITECT® Urine NGAL) in predicting worsening renal function in patients presenting with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON38334

Source
ToetsingOnline

Brief title
AKINESIS

Condition

- Heart failures
- Renal disorders (excl nephropathies)

Synonym
Heart Failure, Kidney Injury

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Abbott Laboratories and Alere

Intervention

Keyword: Acute Decompensated Heart Failure (ADHF), Acute Kidney Injury (AKI), biomarker, Neutrophil Gelatinase Associated Lipocalin (NGAL)

Outcome measures

Primary outcome

Diagnostic:

In patients admitted to the hospital with symptoms of acute heart failure, an elevated plasma or urine NGAL level is predictive of acute kidney injury (AKI), defined by a persistent (>=24 hours) rise in the plasma/serum creatinine level of >=0.5 mg/dl or >=50% above the first creatinine value upon presentation, or the initiation of renal replacement therapy (RRT-including dialysis, ultrafiltration and hemofiltration), during the initial 5 days of hospitalization.

Prognostic:

Patients admitted with symptoms of acute heart failure who have an elevated plasma or urine NGAL level (independent of or in conjunction with changes in plasma/serum creatinine) during hospitalization will have poorer outcomes, defined by a composite index of adverse clinical outcomes following hospitalization at 30 days (with the follow up period starting at enrollment): death, initiation of renal replacement therapy including dialysis, ultrafiltration, and hemofiltration, heart failure-related readmissions, and emergent heart failure-related outpatient visits where IV diuretics are

administered (emergency room, clinic).

Secondary outcome

1. In patients admitted with symptoms of acute heart failure, an elevated plasma or urine NGAL level (independent of or in conjunction with changes in plasma/serum creatinine) during hospitalization will have poorer outcomes, defined by a composite index of adverse clinical outcomes during hospitalization: death, severe AKI [defined by a persistent (>=24 hours) and abrupt (within 5 days) increase in plasma/serum creatinine of >=100% from the first creatinine value upon presentation or initiation of renal replacement therapy including dialysis, ultrafiltration and hemofiltration], respiratory failure requiring mechanical ventilation [invasive or noninvasive], and cardiogenic shock [defined as requiring inotropes or vasopressors].
2. In patients admitted with an estimated glomular filtration rate (eGFR) of <60ml/min/1.73m2 BSA using the MDRD equation, eGFR loss at hospital discharge will be greater in patients who have elevated plasma or urine NGAL level during hospitalization.
3. In patients admitted to the hospital with symptoms of acute heart failure, an elevated plasma or urine NGAL level is predictive of acute kidney injury (AKI), defined by a persistent (>=24 hours) >=50% increase in the plasma/serum creatinine level above the first creatinine value upon presentation occurring within the first 5 days of hospitalization.
4. In patients admitted to the hospital with symptoms of acute heart failure, an elevated plasma or urine NGAL level is predictive of acute kidney injury (AKI), defined by a persistent (>=24 hours) increase in the plasma/serum

creatinine levels of >=0.3 mg/dl or a >=50% increase above the first creatinine value upon presentation occurring in less than 48 hours during the first 5 days of hospitalization.

5. Patients that present with symptoms of acute heart failure that are sent home from the emergency room without admission to the hospital will be followed for 30 days to identify the following events: 1. hospital readmission 2) all cause mortality, 3) and unscheduled visits to the ED or heart failure clinic for worsening heart failure where intravenous diuretics are given. These endpoints will be evaluated in response to the first, peak, and delta plasma and urine NGAL levels. This endpoint is exploratory and there may be insufficient power for analysis.

6. Patients admitted with symptoms of acute heart failure who have an elevated plasma or urine NGAL level (independent of or in conjunction with changes in plasma/serum creatinine) during hospitalization will have decreased organ failure-free survival during their hospitalization, comprising decreased renal failure-free survival, respiratory failure free-survival, cardiovascular failure-free survival, and a composite of all 3 indices.

Data to support the composite index of adverse clinical outcomes at 30 days and 60 days following hospitalization (with the follow-up period starting at enrollment) will be recorded for each subject. Information may come from a family member or friend (if applicable) or by hospital and clinic medical

records. The study site must conduct due diligence in collecting this follow up data as it is part of this study.

Data to support the exploratory analysis of adverse clinical outcomes at 12 months following hospitalization (with the follow-up period starting at enrollment) will be recorded for each subject. Adverse clinical outcomes for the 12 month follow-up will be limited to death, initiation of RRT, and heart failure-related readmissions. Information may come from a family member or friend (if applicable) or by hospital and clinic medical records. The study site must conduct due diligence in collecting this follow up data as it is part of this study.

Study description

Background summary

The development of worsening renal function occurs frequently in the setting of acutely decompensated HF and strongly predicts adverse clinical outcomes. The care of subjects undergoing treatment for acutely decompensated HF could greatly benefit from a test (NGAL) that could aid in identifying subjects at risk of developing worsening renal function. This would potentially permit optimized management of these subjects to protect renal function (i.e., tailored diuretic and fluid management, avoidance of nephrotoxic drugs, minimization of the use of contrast agents, rescheduling of non-emergent surgeries or interventions that might result in additional renal injury, etc.).

Study objective

AKINESIS is a multi-center prospective, uncontrolled clinical study to assess the utility of a plasma NGAL test (Triage® NGAL Test) and a urinary NGAL test (ARCHITECT® Urine NGAL) in predicting worsening renal function in patients presenting with acute heart failure (AHF) who are treated with diuretics.

Study design

This is an obeservational study.

Study burden and risks

Subjects will be asked to provide six urine and blood samples for the purpose of measuring NGAL. Subjects may feel some pain or discomfort during venipuncture when a needle is inserted into the vein of an arm to collect the blood samples. Subjects may also experience bruising, lightheadedness, or on rare occasions, infection at the site of the needle stick. The study poses no special risk to pregnant women or to an unborn fetus.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Subjects must be at least 18 years of age.
•Subjects must present to the hospital with one or more signs or symptoms of acute heart failure (AHF). Signs and symptoms include shortness of breath from walking, rales or crackles, galloping heart rhythm, jugular venous distension, trouble breathing at rest or when lying down, waking breathless at night, using more than 2 pillows to sleep, tiring easily, swelling of feet, ankles or legs, frequent coughing, a cough that produces mucous or blood-tinged sputum, or a dry cough when lying flat.
•Subjects must receive IV diuretics, or there must be an intent to treat with IV diuretics.
•Subjects must be willing and able to comply with all aspects of the protocol.
•Subjects must provide signed informed consent.

Exclusion criteria

•Subjects that present with symptoms consistent with acute coronary syndromes (AMI or UA) as the chief cause of the current episode of AHF.
•Subjects already on dialysis prior to enrollment or if dialysis initiation is already planned during the current hospital visit.
•Subjects that have had any major organ transplant (heart, lung, kidney, or liver).
•Subjects that have participated in a drug treatment study within the past 30 days or if they have already been enrolled as a subject in this study.
•Women who verbally report being pregnant at the time of screening and anyone belonging to a vulnerable population that is deemed inappropriate for inclusion into the study by the IRB/EC.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2011

Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	17-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-01-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01291836
CCMO	NL36031.042.11