Hip fracture Accelerated care and TreaTment trACK (HIP ATTACK)-2

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In patients diagnosed with a hip fracture who also have acute myocardial injury on presentation to hospital, is accelerated surgery superior to standard care for the primary outcome of death at 90 days after randomization?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON51206

Source
ToetsingOnline

Brief title
HIP ATTACK-2

Condition

- Bone and joint therapeutic procedures

Synonym
broken hip, Hip fracture

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Population Health Research Institute (PHRI);Hamilton;Canada.

Intervention

Keyword: Accelerated care, Acute myocardial injury, Hip fracture

Outcome measures

Primary outcome

The primary outcome is all-cause mortality at 90 days after randomization.

Secondary outcome

Functional outcomes: 90-day ability to independently walk 3 metres (10 feet) or across a room without human assistance, and time to first mobilization, standing, and full weight bearing.

Cardiovascular outcomes: composite of major complications (i.e., mortality and non-fatal myocardial infarction, acute congestive heart failure, and stroke); and the following individual secondary outcomes: vascular mortality, non-vascular mortality, myocardial infarction, myocardial injury not fulfilling the definition of myocardial infarction, acute congestive heart failure, and stroke.

Other clinical outcomes: We will also assess the effect of accelerated medical clearance and accelerated surgery compared to standard care on time from randomization to hospital discharge and delirium and moderate to severe pain during the first 7 days after randomization.

Study description

Background summary

Patients suffering a hip fracture with an acute myocardial injury are at substantial risk for mortality. The current standard of care is to delay

surgery for those patients while additional tests and potential treatments are implemented with the intention of minimizing the risk of post-operative complications. However, there is no RCT data demonstrating that cardiac stabilization and surgical delay are beneficial for these patients. Among the patients with an acute myocardial injury randomized to standard care in the HIP ATTACK-1 trial mortality was more than doubled as compared to patients that underwent accelerated surgery.
There exists a strong biological rationale for how accelerated surgical treatment of a hip fracture and an acute myocardial injury may lower a patient*s risk of death. There is also encouraging data from HIP ATTACK-1 trial suggesting that early surgery for a hip fracture reduces a patient*s risk of mortality. Moreover, the HIP ATTACK-1 trial demonstrated the feasibility of a trial comparing accelerated medical assessment and surgery versus standard care in those patients. Currently, most patients wait more than 24 hours to have surgery after diagnosis of a hip fracture when there is an ongoing myocardial injury. The need for a large adequately powered trial to settle the issue in a clear way that will drive subsequent practice is compelling.
This is the first large trial that may change the paradigm to postpone surgery in patients suffering acute myocardial injuries before surgery, proposing a novel approach to reverse myocardial injury through expedited surgical care.

Study objective

In patients diagnosed with a hip fracture who also have acute myocardial injury on presentation to hospital, is accelerated surgery superior to standard care for the primary outcome of death at 90 days after randomization?

Study design

The HIP ATTACK-2 trial is an investigator-initiated, multicentre, international, open-label, RCT that will include 1100 patients presenting with a hip fracture and an acute heart injury. Patients will be randomized to accelerated medical assessment and surgical repair (i.e., goal of surgery within 6 hours of hip fracture diagnosis) or standard care (i.e., medical management of the heart injury and then surgery when the acute heart injury has stabilized). We hypothesize that accelerated surgery is superior to medical management for the primary outcome of death at 90 days after randomization.

Intervention

The planned trial intervention consists of accelerated medical clearance and surgery (i.e., goal of surgery within 6 hours of hip fracture diagnosis). Our objective with accelerated surgery is to facilitate surgery as quickly as possible. We have selected a goal of 6 hours because we know this is a substantial improvement beyond standard care and achieving this target is feasible, based on the HIP ATTACK-1 trial. The control group will receive

standard care (i.e., medical management and cardiac stabilization of the myocardial injury, and performing surgery according to usual timing based on local institution practices), usually >24 hours after the hip fracture diagnosis.
Patients randomized to accelerated care will undergo medical clearance by a dedicated HIP ATTACK-2 medical specialist (e.g., medical specialist would include internal medicine specialist, perioperative care physician, cardiologist, or anaesthetist), who will be available to quickly arrive in the ED for the assessment. This specialist will use their own judgement regarding management when considering any medical conditions that they identify, and they will weigh the potential benefits of delaying surgery for medical management versus the potential negative consequences of protracted exposure to the inflammatory, hypercoagulable, stress, and catabolic states associated with a hip fracture. The HIP ATTACK-2 specialist will assess patients regarding ongoing cardiovascular symptoms (e.g., chest pain), ECG ischemic changes, signs of acute congestive heart failure or cardiogenic shock. After medical clearance, the orthopedic surgeon and anaesthesiologist have to agree that the patient is appropriate for surgery in order for the case to proceed. Patients randomized to accelerated care who are receiving therapeutic dose vitamin K antagonist anticoagulant will receive Prothrombin Complex Concentrate, where available and appropriate.
Patients randomized to accelerated care, after obtaining medical clearance, should be accommodated into the next orthopedic operating room slot. Immediately after medical clearance is obtained, research personnel will inform all the relevant stakeholders (i.e., surgical booking clerk, orthopedic surgeon, and anesthesiologist).
Patients randomized to standard care will undergo medical management of the acute myocardial injury based on local standard practices. The medical management may include medical management of the acute myocardial injury (e.g., aspirin, statin, beta-blockers, ACE inhibitors), additional tests and observation of the heart injury (e.g., serial troponin measurements, serial ECGs, preoperative Echocardiogram), and then hip surgery when the acute heart injury has stabilized (i.e., typically >24 hours after diagnosis). After the patient is medically cleared, they will be waitlisted for surgery according to local standard care.

Study burden and risks

There is a potential risk that accelerated surgery patients may have another preoperative acute medical condition missed that could benefit from medical optimization before surgery (Appendix 2 presents a list of acute medical conditions likely to benefit from medical optimization prior to surgery). For example, the myocardial injury could be in fact a high-risk acute coronary syndrome (i.e., acute myocardial infarction with a mechanical complication [i.e., acute papillary muscle rupture, ventricular septal defect], ST-elevation myocardial infarction, cardiogenic shock) that may benefit from medical optimization. We specified these conditions as one of the exclusion criteria

for the trial. The same HIP ATTACK-1 protocol will be implemented where at each site a medical specialist will clear the patient before surgery, and the anaesthesiologist and the surgeon will have to also approve these patients for surgery.
In HIP ATTACK-1 only 9 of the 2970 patients had an acute severe medical condition from hospital arrival to randomization (i.e., acute myocardial infarction with a mechanical complication, ST-elevation myocardial infarction, cardiogenic shock, stroke, subarachnoid hemorrhage, pulmonary embolus, coronary revascularization, any condition resulting in dialysis, presumptive bacteremia, and respiratory failure requiring mechanical ventilation). Moreover, a pre-specified subgroup analysis did not demonstrate association with higher mortality (HR 0.92; CI 95% 0.73-1.16 in patients with no acute medical condition vs. HR 0.34; CI 95% 0.03-3.41 in patients with acute medical condition; p value for interaction 0.36) or a composite of major complications comparing patients in the accelerated care group and standard care group (HR 0.98; CI 95% 0.84-1.14 in patients with no acute medical condition vs. HR 0.30; CI 95% 0.03-2.75 in patients with acute medical condition; p value for interaction 0.19). A post-hoc subgroup analysis including an expanded list of acute medical conditions demonstrated similar results for mortality (HR 0.91; CI 95% 0.71-1.16 in patients with no expanded acute medical condition vs. HR 0.82; CI 95% 0.41-1.66 in patients with expanded acute medical condition; p value for interaction 0.78), or for a composite of major complications comparing patients in the accelerated care group and standard care group (HR 0.96; CI 95% 0.82-1.13 in patients with no expanded acute medical condition vs. HR 1.00; CI 95% 0.57-1.73 in patients with expanded acute medical condition; p value for interaction 0.93).
Patients randomized to standard care will receive care according to usual local practices, and as such these patients are not at increased risk of complications compared to patients not participating in the trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1) age >=45 years;
2) diagnosis of hip fracture during working hours with a low-energy mechanism requiring surgery;
3) troponin elevation on hospital arrival (at least one troponin level from hip fracture occurrence to randomization above the upper limit of normal); and
4) written informed consent.

Exclusion criteria

1) taking a therapeutic dose of an anticoagulant for which no reversing agent is available;
2) patients on a therapeutic vitamin K antagonist with a history of heparin induced thrombocytopenia (HIT);
3) patients with peri-prosthetic fracture, open fracture or bilateral fractures;
4) patients requiring an emergency surgery for another reason (e.g., subdural hematoma);
5) patients with acute myocardial infarction with a mechanical complication (i.e., acute papillary muscle rupture, ventricular septal defect), ST elevation myocardial infarction, or cardiogenic shock;
6) patients refusing consent; or
7) patients previously enrolled in HIP ATTACK-2.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2022
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-11-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-01-2024
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	NCT04743765
CCMO	NL77474.075.21