The ATACAS Trial: Aspirin and Tranexamic Acid for Coronary Artery Surgery Trial. A prospective, randomised, double blind, factorial trial testing whether aspirin, tranexamic acid, or both, can reduce mortality and/or major morbidity after elective coronary artery surgery.

Published: 27-03-2014
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Should low-dose aspirin be continued up until the day of CABG or OPCAB surgery?Should TxA be used for all at-risk CABG or OPCAB surgery?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON40015

Source
ToetsingOnline

Brief title
ATACAS Trial

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
CABG, heart bypass surgery

Research involving
Human

Sponsors and support

Primary sponsor: Alfred Hospital
Source(s) of monetary or material Support: Opdrachtgever (Australian NHMRC Project Grant (ID 334015))

Intervention

Keyword: Aspirin, CABG, Cardiac Surgery, Tranexamic Acid

Outcome measures

Primary outcome

Composite: 30-day mortality or major morbidity (myocardial infarction,

cardiogenic shock, stroke, pulmonary embolism, cardiac tamponade).

Secondary outcome

Each of the above, plus blood transfusion, re-operation, respiratory failure,

renal failure, serious wound infection, prolonged hospitalisation.

Study description

Background summary

There are more than 10,000 cardiac surgery cases done each year in The Netherlands. About 5% have a serious complication or die; this adds substantially to healthcare costs. Cardiac surgery activates platelets and coagulation factors, and the fibrinolytic pathway. Excessive bleeding is common. This may require surgical re-exploration and increases morbidity and mortality. Recent aspirin exposure increases surgical bleeding. It is routine practice in most cardiac surgical centres for aspirin to be ceased 1 wk before elective cardiac surgery. But a recent landmark study found that aspirin had a lower mortality, as well as less stroke, renal failure and bowel infarction (all $P<0.01$), presumably because of its anti-thrombogenic effects.

Another drug, Tranexamic Acid (TxA), is sometimes used to reduce bleeding after cardiac surgery. It works by blocking the activation fibrinolysis ("clot breakdown") that often occurs during bypass and surgery. It can block the bleeding risk associate with aspirin, and does not increase thrombotic risk. Meta-analyses of trials have shown that antifibrinolytic therapy reduces blood loss, need for blood transfusion and re-operation for bleeding in cardiac surgery. Such therapy may also reduce mortality. Large outcome trial data are lacking.

Study objective

Should low-dose aspirin be continued up until the day of CABG or OPCAB surgery? Should TxA be used for all at-risk CABG or OPCAB surgery?

Study design

Large, multi-centre, prospective,randomised, double blind, factorial trial. Patients will be randomly allocated to aspirin, Tranexamic Acid, aspirin + Tranexamic Acid or placebo.

Intervention

On the morning of surgery patients are randomised to one of 4 groups:
Group 1 = Aspirin
Group 2 = Tranexamic acid
Group 3 = Aspirin plus tranexamic acid
Group 4 = Placebo

Study burden and risks

Patients get the usual care around their CABG procedure. The use of aspirin and Tranexamic Acid is standard of care in the UMC Utrecht. Sampling of blood for study purposes is combined with regular blood sampling. Participation is not causing extra burden for the patient.

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

1. Males and females, age 18 years and over
2. Written, informed consent
3. Elective coronary artery surgery (on-pump or off-pump)
4. Patient is at increased risk of major complications, defined by any of:
* Age 70 years and over
* Left ventricular impairment (fractional area change <20%, ejection fraction <40%, or at least moderate impairment on ventriculography)
* Concomitant valvular or aortic surgery
* Aneurysmectomy
* Repeat cardiac surgery (*re-do*)
* Chronic obstructive pulmonary disease
* Renal impairment (se. creatinine >150 *mol/l or creatinine clearance <45 ml/min)
* Obesity (body mass index >25 kg/m2)
* Pulmonary hypertension (mPAP >25 mmHg)
* Peripheral vascular disease.

Exclusion criteria

1. Poor (Dutch) language comprehension
2. Clinician preference for antifibrinolytic therapy
3. Urgent surgery for unstable coronary syndromes where for clinical reasons antiplatelet

medication cannot be discontinued
4. Active peptic ulceration
5. Allergy or contraindication to aspirin or tranexamic acid
6. Aspirin therapy within 4 days of surgery
7. Warfarin or clopidogrel therapy within 7 days of surgery, or GIIb/IIIa antagonists within 24 h of surgery
8. Thrombocytopaenia or any other known history of bleeding disorder
9. Severe renal impairment (serum creatinine >250 *mol/l, or estimated creatinine clearance <25 ml/min)
10. Recent haematuria
11. Thromboembolic disease relating to: history of postoperative or spontaneous pulmonary embolism, spontaneous arterial thrombosis or familial hypercoaguability (eg. Lupus anticoagulant, protein C deficiency)
12. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2014
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	27-03-2014

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	ACTRN 12605000555651
CCMO	NL39627.041.13

Study results

Date completed:	15-10-2016
Actual enrolment:	29

Summary results
Trial is onging in other countries