Dexamethasone for Cardiac Surgery study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19963

Source
Nationaal Trial Register

Brief title
DECS trial

Health condition

1. Cardiac surgery (Hartchirurgie);

2. Systemic Inflammatory Response Syndrome (SIRS).

Sponsors and support

Primary sponsor: UMC Utrecht, Division of Perioperative Care & Emergency Medicine (Prof.dr. C.J. Kalkman)
Source(s) of monetary or material Support: Nederlandse Hartstichting (NHS) Zorgonderzoek Nederland, Medische Wetenschappen (ZonMw)

Intervention

Outcome measures

Primary outcome

The primary endpoint is the occurrence of major complications (including all-cause mortality,

myocardial infarction, stroke, renal failure, and prolonged mechanical ventilation) in the first 30 days after surgery.

Secondary outcome

1. The occurrence of one or more major complications within the first year after surgery;

2. the separate components of the primary outcome measure, i.e. major complications in the first 30 days after surgery;

3. quality of life at 30 days and one year after surgery;

4. wound infection in the first 30 days after surgery;

5. use of anti-anginal drugs at 30 days after surgery;

6. atrial fibrillation in ICU;

7. highest serum glucose concentration in ICU;

8. use of inotropes on the first postoperative day;

9. highest body temperature in ICU;

10. time to extubation;

11. time to discharge from ICU;

12. time to discharge from hospital;

13. change in cognitive performance from before to 30 days after surgery (subsample of 400 patients);

14. serum glucose-values and insulin use in ICU (subsample of patients in the UMC Utrecht);

15. cost-effectiveness analysis.

Study description

Background summary

Rationale

Cardiac surgery is associated with a postoperative systemic inflammatory response syndrome, which may contribute to mortality, myocardial infarction and other major complications. The inflammatory response can be suppressed with high dose corticosteroids, typically an intraoperative intravenous injection of dexamethasone 1 mg/kg. The use of high dose corticosteroids, however, can have a multitude of unwanted side effects including immunosuppression, poor wound healing, inadequate glucose control, fluid retention, hypertension, electrolyte imbalances, higher lactate levels, and gastrointestinal blood loss. These side effects themselves could contribute to the rate of major complications. At present, there is no evidence from clinical trials whether steroids increase or decrease the risk of major perioperative complications. As a result, the use of steroids in heart surgery is highly controversial and varies greatly across the countries where heart surgery is performed.

Study Objective

To determine whether the proportion of patients with one or more major complications (mortality, myocardial infarction, stroke, renal failure and prolonged mechanical ventilation) in the first month after cardiac surgery, is reduced by intra-operative administration of dexamethasone. Secondary objectives include an evaluation of the impact of dexamethasone on major complications at 1 year follow-up.

Study Design

This is a large but simple multi-centre, double-blinded, randomized controlled trial of dexamethasone versus placebo in 4,500 adult patients undergoing cardiac surgery.

Eligibility

Patients are eligible if they are undergoing cardiac and are 18 years or older.

Study Drug Administration

Patients will be randomized to receive a single intravenous injection of dexamethasone 1 mg/kg, or a single intravenous injection of placebo, immediately after induction of anesthesia.
Trial medication (dexamethasone or placebo) is administered by the attending anesthetist.

Patients and treating physicians are blinded for treatment allocation.

Follow-up

A limited set of data will be collected during the patient’s hospital stay. The occurrence of one or more major complications will be determined at the 30th day after surgery. There will also be a long term follow-up at 1 year.

Study objective

A single, prophylactic dose of dexamethasone during cardiac surgery reduces the incidence of major postoperative complications.

Study design

1. 30 days (prim);

2. 1 year (sec).

Intervention

Administration of dexamethasone 1 mg/kg, or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

All types of cardiac surgery in which cardiopulmonary bypass is used.

Exclusion criteria

1. Age under 18 years;

2. Life-expectancy <6 months;

3. Emergency operations;

4. Re-operations within the same admission.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2006
Enrollment:	4500
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-10-2007
Application type:	First submission

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
NTR-new	NL1069
NTR-old	NTR1102
Other	UMC Utrecht, DP&S : DECS
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A