Dexamethasone for Cardiac Surgery study

Gepubliceerd: 21-10-2007 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19963

Bron
NTR

Verkorte titel
DECS trial

Aandoening

1. Cardiac surgery (Hartchirurgie);

2. Systemic Inflammatory Response Syndrome (SIRS).

Ondersteuning

Primaire sponsor: UMC Utrecht, Division of Perioperative Care & Emergency Medicine (Prof.dr. C.J. Kalkman)
Overige ondersteuning: Nederlandse Hartstichting (NHS)
Zorgonderzoek Nederland, Medische Wetenschappen (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

1. 30 days (prim);

2. 1 year (sec).

Onderzoeksproduct en/of interventie

Administration of dexamethasone 1 mg/kg, or placebo.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age under 18 years;

2. Life-expectancy <6 months;

3. Emergency operations;

4. Re-operations within the same admission.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2006
Aantal proefpersonen:	4500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-10-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1069
NTR-old	NTR1102
Ander register	UMC Utrecht, DP&S : DECS
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A