

# Intensive insulin therapy does not alter the inflammatory response in patients undergoing coronary artery bypass graft (CABG): a randomized controlled trial

<b>Submission date</b> 24/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/11/2007	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
CH0401

# Study information

## Scientific Title

## Acronym

CH0401

## Study objectives

Strict glucose control in critically ill patients alters the cytokine balance towards a more pro-inflammatory state.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Coronary artery bypass graft

## Interventions

Strict glucose control (blood glucose between 80-110 mg/dl) versus placebo (blood glucose >200 mg/dl).

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Insulin

**Primary outcome measure**

Cytokine levels

**Secondary outcome measures**

Complement concentration

**Overall study start date**

01/09/2003

**Completion date**

01/11/2004

## **Eligibility**

**Key inclusion criteria**

1. Adults, after uncomplicated CABG
2. Non-diabetics

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. Diabetes
2. Renal failure
3. Use of anti-inflammatory drugs
4. Recent myocardial ischemia

**Date of first enrolment**

01/09/2003

**Date of final enrolment**

01/11/2004

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**  
**Geert Grooteplein 10**  
Nijmegen  
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## **Sponsor information**

### **Organisation**

Radboud University Nijmegen Medical Centre (The Netherlands)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/05wg1m734>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

The Department of Intensive Care, Radboud University Nijmegen Medical Centre

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/09/2005		Yes	No