

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

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Cytokine levels

Key secondary outcome(s)

Complement concentration

Completion date

01/11/2004

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Netherlands

6500 HB

Sponsor information**Organisation**

Radboud University Nijmegen Medical Centre (The Netherlands)

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

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?
Results article	Results	01/09/2005		Yes	No