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Pre-operative volume replacement versus usual care in diabetic patients having coronary artery bypass graft (CABG) surgery: a randomised controlled trial

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Registration date 29/10/2008	**Overall study status** Completed	
Last Edited 23/09/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Raimondo Ascione

Contact details
Bristol Heart Institute
Level 7 Queens Building
Bristol Royal Infirmary (BRI)
Marlborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 34 23286
r.ascione@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pre-operative volume replacement versus usual care in diabetic patients having coronary artery bypass graft (CABG) surgery: a randomised controlled trial

Acronym
VeRDiCT

Study objectives
Post-operative incidence of renal insufficiency is lower and post-operative recovery faster, when diabetic patients are treated with volume replacement therapy (VR) prior to surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Somerset & South Bristol REC, 25/02/2010, ref: 10/H0106/1

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary heart disease and diabetes

Interventions
Current interventions as of 01/05/2012
1. Volume replacement: CABG with or without cardiopulmonary bypass (CPB), with preoperative volume replacement therapy (1 ml/kg/hr of Hartmann's solution for 12 consecutive hours prior

to surgery).
2. Usual care: CABG with or without CPB with conventional preoperative management (no preoperative fluids).

Previous interventions
The participants will be randomly allocated to the following two treatment groups in equal numbers:
1. Volume replacement: CABG with or without CPB, with pre-operative volume replacement therapy (1 ml/kg/hr of normal saline [N/saline] for 12 consecutive hours prior to surgery)
2. Usual care: CABG with or without CPB with conventional pre-operative management (no pre-operative fluids)

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 15/05/2009:
Time until patients are classified as 'fit for discharge' since renal impairment is expected to impact on the risk of many post-operative complications. A patient must have normal temperature, pulse and respiration, normal oxygen saturation on air, normal bowel function and be physically mobile in order to be classified as fit for discharge.

Previous primary outcome measures:
Time until patients are classified as 'fit-for-discharge' since renal impairment is expected to impact on the risk of many post-operative complications. In order to be classified as fit for discharge, a patient must have a chest X-ray with no evidence of pleural effusion requiring drainage, lung collapse/consolidation or pneumothorax, no suspected infection, normal routine blood tests and temperature and be physically mobile.

Secondary outcome measures
Current secondary outcome measures as of 08/04/2013 (changes implemented as of 16/01 /2013):
1. A participants judgement about his or her readiness for discharge when the above criteria are met (too soon, about right, could have been discharged earlier);
2. Estimated GFR (eGFR) from serum creatinine measured from blood samples collected preoperatively (baseline, pre-trial intervention), and at 0, 12, 24, 36, 48, 72, 96 and 120 hours after the operation and the % of participants with GFR<60 mL/min on 2 of the 8 post-operative times;
3. Microalbumin/creatinine ratio measured in urine samples collected preoperatively (baseline, pre-trial intervention) and at 0, 24, 48 and 120 hours to assess microvascular disease and renal glomerular injury.
4. Tubular injury as expressed by N-acetyl glucosaminidase (NAG) release measured in urine samples collected preoperatively (baseline, pre-trial intervention) and at 0, 24, 48 and 120 hours in a consecutive sub-sample of 50 patients.
5. Acute Kidney Injury (AKI, doubling of baseline serum creatinine at any time); serum creatinine will be measured from blood samples collected preoperatively (baseline, pre-trial intervention) and at 0, 24, 48, 72, 96, and 120 hours; the peak of postoperative serum creatinine level will be used in relation to the preoperative value to calculate the incidence of AKI;
6. In-hospital mortality and other standard measures of morbidity as used in previous RCTs, e.g. post-operative myocardial infarction (MI), stroke, arrhythmia, need for haemodynamic support, renal failure and wound infection (including 6-8 week telephone ASEPSIS assessment);

7. Use of health care resources and associated costs, e.g. duration of operation, intensive care unit (ICU)/high dependency unit (HDU) and ward stay, additional interventions to treat complications, readmissions;
8. Coronary Revascularisation Outcome Questionnaire (CROQ) preoperatively (preoperative version) and at 3 months.
9. The following outcomes will be measured in a consecutive sub-sample of 40 patients.
9.1. Preoperative blood glucose control, as measured by fasting blood glucose and haemoglobin A1c (HbA1c) prior to chest opening but after the intervention.
9.2. MicroRNA and other biochemical predictors of health outcome in serum and plasma taken preoperatively (baseline, pre-trial intervention) and at 0, 24 and 120 hours after the operation, and also in any leftover material/specimens collected during surgery (this may include, but is not limited to: portions of internal mammary arteries with surrounding tissues, pericardial fluid, pericardial fat/adipose tissue, pericardium, waste blood).
9.3. C-reactive protein as a marker of inflammation, measured preoperatively (baseline, pre-trial intervention) and at 0, 12, 24, 48, 72 and 120 hours after the operation.
9.4. Cardiac damage as measured with serial troponin T release measured pre-operatively (baseline, pre-trial intervention) and at 0, 12, 24, 48, 72 and 120 hours after the operation.

Previous secondary outcome measures as of 01/05/2012:
1. A participant's judgement about his or her readiness for discharge when the above criteria are met (too soon, about right, could have been discharged earlier)
2. Estimated GFR from serum creatinine measured from blood samples collected preoperatively, and at 0, 12, 24, 36, 48, 72, 96 and 120 hours after the operation) and the % of participants with GFR <60 mL/min on 2 of the 8 post-operative times
3. Microalbumin/creatinine ratio measured in urine samples collected preoperatively and at 0, 24, and 48 hours to assess microvascular disease and renal glomerular injury
4. Tubular injury as expressed by by N-acetyl glucosaminidase (NAG) release measured in urine samples collected preoperatively and at 0, 24, and 48 hours in a consecutive sub-sample of 80 patients.
5. Acute Kidney Injury (AKI, doubling of baseline serum creatinine at any time); serum creatinine will be measured from blood samples collected preoperatively and at 0, 24, 48, 72, 96, and 120 hours; the peak of postoperative serum creatinine level will be used in relation to the preoperative value to calculate the incidence of AKI
6. In-hospital mortality and other standard measures of morbidity as used in previous RCTs, e.g., post-operative MI, stroke, arrhythmia, need for haemodynamic support, renal failure and wound infection (including 4-6 week telephone ASEPSIS assessment)
7. Use of health care resources and associated costs, e.g., duration of operation, ICU/HDU and ward stay, additional interventions to treat complications, readmissions
8. Coronary Revascularisation Outcome Questionnaire (CROQ) preoperatively (preoperative version) and at 3 months

Previous secondary outcome measures as of 15/05/2009:
1. A participant's judgement about his or her readiness for discharge when the above criteria are met (too soon, about right, could have been discharged earlier)
2. Estimated GFR from serum creatinine measured from blood samples collected preoperatively, and at 0, 12, 24, 36, 48, 72, 96 and 120 hours after the operation) and the % of participants with GFR <60 mL/min on 2 of the 7 post-operative times
3. Microalbumin/creatinine ratio measured in urine samples collected preoperatively and at 0, 24, and 48 hours to assess microvascular disease and renal glomerular injury
4. Tubular injury as expressed by by N-acetyl glucosaminidase (NAG) release measured in urine samples collected preoperatively and at 0, 24, and 48 hours in a consecutive sub-sample of 80 patients.

5. Acute Kidney Injury (AKI, doubling of baseline serum creatinine at any time); serum creatinine will be measured from blood samples collected preoperatively and at 0, 24, 48, 72, 96, and 120 hours; the peak of postoperative serum creatinine level will be used in relation to the preoperative value to calculate the incidence of AKI
6. In-hospital mortality and other standard measures of morbidity as used in previous RCTs, e.g., post-operative MI, stroke, arrhythmia, need for haemodynamic support, renal failure and wound infection (including 4-6 week telephone ASEPSIS assessment)
7. Use of health care resources and associated costs, e.g., duration of operation, ICU/HDU and ward stay, additional interventions to treat complications, readmissions
8. Coronary Revascularisation Outcome Questionnaire (CROQ) preoperatively (preoperative version) and at 3 months

Previous secondary outcome measures:
1. A participant's judgment about his or her readiness for discharge when the above criteria are met (too soon, about right, could have been discharged earlier)
2. Estimated glomerular filtration rate (GFR) from serum creatinine measured from blood samples collected pre-operatively, and at 0, 4, 12, 24 and 48 hours after the operation) and the percentage of participants with GFR less than 60 mL/min on two of the five post-operative times
3. Renal glomerular and tubular injury as expressed by microalbumin/creatinine ratio and by N-acetyl glucosaminidase (NAG) release respectively and measured in urine samples collected pre-operatively and at 0, 24, and 48 hours in a consecutive sub-sample of 80 patients
4. Acute renal failure (ARF) (doubling of baseline serum creatinine at any time). Serum creatinine will be measured from blood samples collected pre-operatively and at 0, 24, 48, 72, 96, and 120 hours; the peak of post-operative serum creatinine level will be used in relation to the pre-operative value to calculate the incidence of ARF
5. In-hospital mortality and other standard measures of morbidity as used in previous randomised controlled trials, e.g., post-operative myocardial infarction (MI), stroke, arrhythmia, need for haemodynamic support, renal failure and wound infection (including 4 - 6 week telephone ASEPSIS assessment)
6. Use of health care resources and associated costs, e.g. duration of operation, intensive care unit (ICU)/high dependency unit (HDU) and ward stay, additional interventions to treat complications, readmissions
7. Coronary Revascularisation Outcome Questionnaire (CROQ) pre-operatively (pre-operative version) and at 3 months

Overall study start date
01/06/2009

Completion date
31/08/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/05/2009:
1. Patients with diagnosed type I or type II diabetes, being treated with oral medication and/or insulin (i.e. not diet controlled only)
2. Both males and females, age >16 and <80 years
3. Undergoing elective or urgent, isolated first time coronary artery bypass graft (CABG) with or without cardiopulmonary bypass (CPB)
4. Left ventricular ejection fraction >=30%

Previous inclusion criteria:
1. Patients with diagnosed type I or type II diabetes
2. Both males and females, aged greater than 16 and less than 80 years
3. Undergoing elective or urgent, isolated first time coronary artery bypass graft (CABG) with or without cardiopulmonary bypass (CPB)
4. Left ventricular ejection fraction greater than or equal to 25%

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
170

Total final enrolment
169

Key exclusion criteria
1. Patients who have had previous cardiac surgery
2. Emergency or salvage operation
3. Chronic renal failure requiring dialysis
4. Current congestive heart failure
5. Left ventricular ejection fraction <30% (i.e. poor LV function)

Please note that the 5th exclusion criterion was updated as of 15/05/2009. The previous criterion was as follows:
5. Left ventricular ejection fraction less than 25%

Date of first enrolment
01/06/2009

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Bristol Heart Institute
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details
Research and Innovation
Education Centre Level 3
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/research-innovation/

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Charity

Funder Name
Garfield Weston Foundation (UK)

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?
Protocol article	protocol	19/06/2017		Yes	No
Results article	results	01/01/2020	23/09/2019	Yes	No
HRA research summary			28/06/2023	No	No