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Risk model to predict adverse outcomes after primary percutaneous coronary intervention (PCI)

Submission date 22/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2008	**Overall study status** Completed	
Last Edited 28/10/2013	**Condition category** Circulatory System	

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
N/A

Study information

Scientific Title
Development and validation of a risk scoring model to predict net adverse cardiovascular outcomes after primary percutaneous coronary intervention (PCI) in patients pretreated with 600 mg clopidogrel, rationale and design of the RISK-PCI study

Acronym
RISK-PCI

Study objectives
The primary hypothesis of the trial is that an accurate prediction of net adverse cardiovascular outcomes (NACE) at presentation may result in a significant reduction of NACE after primary percutaneous coronary intervention (pPCI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by a Local Research Ethics Committee of the School of Medicine, University of Belgrade on the 21st February 2008 (ref: No 470/II-4).

Study design
Observational, longitudinal, cohort, single-centre trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Acute ST elevation myocardial infarction

Interventions
Recruitment for this study began on the 1st February 2006. The completion of enrolment is expected in summer 2009.

The first 1,166 consecutive patients will enter the study set, while the further 584 patients will enter the validation set. Risk factors and scores derived from the study set will be tested in the validation set. Primary PCI and stenting of the infarction-related artery (IRA) is performed according to standard technique via femoral approach. Flow grades are assessed according to TIMI criteria. Procedural success is defined as Thrombolysis in Myocardial Infarction-3 (TIMI-3) flow and <30% stenosis after intervention. Drug-eluting stents (DES) are encouraged in selected patients with in-stent restenosis, diabetes mellitus, very long or bifurcation lesions.

Before pPCI, 300 mg aspirin and 600 mg clopidogrel are administered to all eligible patients. Unfractionated heparin is started as 60 IU/kg bolus; the 12 U/kg/h infusion follows during the next 24 hours in uncomplicated patients or longer if clinically indicated. The dose is based on the activated Partial Thromboplastin Time (PTT). 40 mg proton-pump inhibitor pantoprazol or 50 mg H2-blocker ranitidine are given intravenously to all patients before pPCI; a peroral treatment follows (40 mg pantoprazol/day or 50 mg ranitidine/day) during the next 2-3 days. Enoxiparin sodium (100 anti-Xa IU/kg every 12 hours) is used subcutaneously in patients under 75 years who failed to reach the therapeutic aPTT with standard heparin treatment, those who did not receive GP IIb/IIIa inhibitor, and those with renal failure (creatinine clearance <60 ml/min). In selected patients with visible intracoronary thrombi, GP IIb/IIIa receptor inhibitor tirofiban - the dose based on body weight (25 µg/kg bolus followed by 18- to 24-hour 0.15 µg/kg/min infusion), adjusted for renal impairment (half of the usual infusion dose if creatinine clearance <60 ml/min) - is administered during the pPCI. Aspirin, clopidogrel, beta-blockers, lipid-lowering agents and ACE inhibitors are used after pPCI, according to current guidelines. Patients who show clinical signs of heart failure are treated with digitalis, diuretics, or inotropic agents at the discretion of investigators. Bleeding patients are treated with blood product transfusion if haemoglobin is <10 g/dL. If necessary, one or both antiplatelet agents will be discontinued.

Temporary pacemaker is placed in all patients with high-grade AV block or bradiarrhythmia and hemodynamic compromise. Intra-aortic balloon pump is used in patients who progress to Killip IV heart failure. If bleeding is life-threatening, surgery may be performed.

Patients are followed-up at 30 days and at 1 year after enrolment, on the intention-to-treat principle. Follow-up data are obtained by telephone interviews.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Risk score for composite major adverse cardiac events (MACE) including death, nonfatal reinfarction, ischaemic stroke and target vessel revascularisation (efficacy endpoint)
2. Risk score for major bleeding (safety endpoint)

Secondary outcome measures
Efficacy:
1. Individual components of MACE
2. Stent thrombosis

Safety:
3. Incidence of bleeding according to the TIMI and GUSTO classification

4. Need for transfusions
5. Withdrawal of dual antiplatelet therapy

Overall study start date
01/02/2006

Completion date
01/07/2009

Eligibility

Key inclusion criteria
1. Both males and females, 18 years of age or older
2. Chest discomfort persisting for more than 20 minutes
3. Presentation within 12 hours after the onset of symptoms
4. ST elevation in two contiguous leads of at least 0.2 mV in leads V2V3 and/or of at least >0.1 mV in other leads, or new bundle branch block
5. Cardiac troponin exceeding upper reference limit at admission and/or 24 hours later

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,750

Key exclusion criteria
1. Refusal to give consent for invasive treatment
2. Contraindications for dual antiplatelet therapy or contrast agents (active or recent internal bleeding, history of bleeding after non-steroid anti-inflammatory agents, known bleeding diathesis, allergy, intracerebral mass or aneurysm, platelet count of <100,000/mm^3
3. Cardiogenic shock at admission
4. Noncardiac conditions that could limit life expectancy to less than 1 year or that might interfere with compliance with the protocol (active cancer, significant liver or renal disease [creatinine clearance <30 ml/min], significant psychiatric disorders)
5. Planned elective surgery necessitating interruption of treatment with thienopyridines during the first 6 months after enrolment

Date of first enrolment
01/02/2006

Date of final enrolment

01/07/2009

Locations

Countries of recruitment
Serbia

Study participating centre
Klinicki Centar Srbije
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Sponsor information

Organisation
Clinical Center of Serbia (Serbia)

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Sponsor type
Hospital/treatment centre

Website
http://www.icvd-kcs.org

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clinical Center of Serbia, Institute for Cardiovascular Diseases, Cardiology Clinic (Serbia)

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?
Other publications	incidence, predictors, and 30-day outcomes	01/01/2012		Yes	No
Results article	results	20/01/2013		Yes	No