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Naproxen as prophylaxis against atrial fibrillation after coronary artery bypass graft surgery

Submission date 25/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/10/2007	**Overall study status** Completed	
Last Edited 10/06/2021	**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
Naproxen as prophylaxis against atrial fibrillation after coronary artery bypass graft surgery

Acronym
NAFARM

Study objectives
Postoperative atrial fibrillation occurs in 25 to 40 percent of patients undergoing Coronary Artery Bypass Graft (CABG) surgery. Although prophylactic therapy with beta-adrenergic blockers and amiodarone reduces the incidence of postoperative atrial fibrillation, this arrhythmia remains an important cause of increased hospital mortality, stays and expenses after CABG surgery. There is mounting evidence to support the influence of inflammation (increased levels of C-reactive protein, interleukin-6, tumour necrosis factor, atrial myocarditis and pericarditis) in the pathogenesis of postoperative atrial fibrillation. Naproxen is a nonsteroidal anti-inflammatory drug that has a role in inflammation and can have an effect on postoperative atrial fibrillation.

Hypothesis: Naproxen reduces the incidence of postoperative atrial fibrillation after coronary artery bypass graft surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Pontificia Catholic University of Rio Grande do Sul (Pontificia Universidade Catolica do Rio Grande do Sul) Human Research Committee and Brazilian National Ethics Committee on Research (CONEP) on 09/01/2004 (ref: 0232.0.002.000-04)

Study design
Single-centre, double-blind, randomized controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
The patients are interviewed on the day of their initial evaluations in the cardiac surgery unit at the Sao Lucas da PUCRS Hospital. They are randomly assigned in a double-blind fashion to begin oral therapy immediately after their CABG surgery. Each patient is admitted to an intensive care unit and is monitored on Marquette HelligeVicom-SM ICU monitor. Naproxen/placebo are administered at a dosage of 275 mg two times a day for five days. The placebo tablets are identical in appearance to the naproxen tablets. The patients receive a nasogastric tube while mechanical ventilation to receive the study medication. If the patient has risk factors for gastrointestinal bleeding (age above 60 years, history of peptic ulcer disease, use of glucocorticoids or oral anticoagulant) he receives concomitant Omeprazole 20 mg, one tablet orally each day. The investigator evaluates the patients daily. After discharge from the intensive care unit the patient is monitored with 12-lead electrocardiogram and by the investigator for symptoms.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
The incidence of postoperative atrial fibrillation, determined within 5 days of the patient's coronary artery bypass graft surgery. Atrial fibrillation is counted if it persists for more than three minutes or the patient develops hemodynamic instability.

Secondary outcome measures
Overall length of hospital stay and length of stay at the intensive care unit.

Overall study start date
22/11/2004

Completion date
12/04/2008

Eligibility

Key inclusion criteria
1. Informed consent
2. Older than 18 years
3. Scheduled for exclusive coronary artery bypass graft surgery requiring cardiopulmonary bypass
4. Normal sinus rhythm

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
161

Key exclusion criteria
Exclusion criteria amended as of 16/11/2007:
1. Patients who are allergic to naproxen or other nonsteroidal anti-inflammatory drugs
2. Patients who are participating in another investigational trial
3. Pregnant women
4. Renal failure
5. History of gastrointestinal bleeding
6. Chronic liver disease
7. Thrombocytopenia (platelets below 50.000/mm^3)
8. Preoperative use of glucocorticoids
9. Previous diagnosis of atrial fibrillation

Exclusion criteria provided at time of registration:
1. Patients who are allergic to naproxen or other nonsteroidal anti-inflammatory drugs
2. Patients who are participating in another investigational trial
3. Pregnant women
4. Renal failure
5. History of gastrointestinal bleeding
6. Chronic hepatitis
7. Thrombocytopenia (platelets below 50.000/mm^3)

Date of first enrolment
22/11/2004

Date of final enrolment
12/04/2008

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Sinimbu, 2019
Caxias do Sul - Rio Grande do Sul

Brazil
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Sponsor information

Organisation
Sao Lucas da PUCRS Hospital and the Sao Paulo Federal University (Brazil)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.hospitalsaolucas.pucrs.br

ROR
https://ror.org/0353n6963

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Internally funded by the Cardiology Unit of Sao Lucas da PUCRS Hospital (Brazil)

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?
Results article		01/11/2011	10/06/2021	Yes	No