

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

Submission date 25/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2021	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

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/mm³)
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/mm³)

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
95020001

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