

Comparing Warfarin to Aspirin after tissue valve replacement with Epic prosthesis in the aortic position: multicenter randomised trial

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| Submission date 22/09/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 22/09/2004 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 13/11/2007 | Condition category Circulatory System | <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

Acronym

WoA Epic

Study objectives

Patients with prosthetic heart valves have a higher risk of developing valve thrombosis and arterial thromboembolism. However, antithrombotic therapy in the early postoperative period after Biological Aortic Valve Replacement (BAVR) is still controversial. Many regimens have been described. Thus, the aim of this study will be to compare the validity of two different regimens of therapy in the early postoperative period after BAVR with St Jude Epic prosthesis, and to evaluate the benefits, particularly in terms of survival and cerebral protection from thromboembolism and major bleeding.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Biological Aortic Valve Replacement

Interventions

Patients will receive a specific regimen of therapy according to the result of randomisation. The administration of Low Molecular Weight Heparin (LMWH) will start on the first postoperative day, whereas warfarin and ASA on day 2. In patients receiving warfarin the use of LMWH will be continued until warfarin reached therapeutic levels as shown by a Prothrombin Time (PT) according to the International Normalised Ratio (INR; range 2.0 to 3.0). Anticoagulation with warfarin will be maintained for 3 postoperative months, then will be discontinued and

substituted with ASA. Those with concomitant coronary artery bypass grafting will not receive any double therapy warfarin plus ASA.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Warfarin and aspirin (Acetylsalicylic Acid [ASA])

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2001

Completion date

01/12/2002

Eligibility

Key inclusion criteria

This is a prospective randomised multicenter trial using patients who will be consecutively admitted to Cardiac Surgery Units. All patients undergoing Biological Aortic Valve Replacement (BAVR) with a St Jude Epic prosthesis and in sinus rhythm before the operation will be considered to participate to the study. The patients, after the operation, will be randomised to each group immediately before starting the specific aspirin (Acetylsalicylic Acid [ASA]) or warfarin therapy.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

The patients with the following characteristics will be excluded:

1. History of cerebral ischaemia
2. Coagulopathy

3. Carotid atherosclerotic disease (stenosis greater than 50%, soft and ulcerated plaque)
4. Peripheral vascular disease
5. Concomitant mitral valve disease
6. Double valve replacement
7. Previous chronic anticoagulation therapy
8. Allergies to ASA or warfarin
9. Comparison of atrial fibrillation (AF) at any time during the study except for transient episode during the hospitalisation
10. Promptly cardioverted

Date of first enrolment

01/01/2001

Date of final enrolment

01/12/2002

Locations

Countries of recruitment

Italy

Study participating centre

Via Gramsci 13

Parma

Italy

43100

Sponsor information

Organisation

University of Parma (Italy)

Sponsor details

Cardiac Surgery Unit

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Sponsor type

University/education

Website

<http://www.unipr.it/>

ROR

<https://ror.org/02k7wn190>

Funder(s)

Funder type

Other

Funder Name

Company of Saint Paul (Compagnia di S Paolo) (Italy)

Funder Name

Ministry for Universities and of Scientific and Technological Research (Ministero dell'Università e della Ricerca Scientifica e Tecnologica [MURST]) (Italy)

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? |
|------------------------------------|------------------|--------------|------------|----------------|-----------------|
| Abstract results | PubMed Abstract: | 03/08/2004 | | No | No |
| Other publications | Full text: | 03/08/2004 | | Yes | No |