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

Submission date	Recruitment status	[_] Prospectively registered
22/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/11/2007	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

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 dellUniversità 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