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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
22/09/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/09/2004	Completed	[X] Results
<b>Last Edited</b> 13/11/2007	Condition category Circulatory System	[] Individual participant data

# Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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## Additional identifiers

Protocol serial number 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

## Study type(s)

Treatment

## 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(s)

Not provided at time of registration

## Key secondary outcome(s))

Not provided at time of registration

## 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

## Healthy volunteers allowed

No

## Age group

**Not Specified** 

### Sex

**Not Specified** 

## 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 plague)
- 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)

## **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**

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