Leukocyte Depletion of Autologous Whole Blood: impact on perioperative infection rate and length of hospital stay for hip arthroplasty patients

Submission date	Recruitment status No longer recruiting	Prospectively registered	
29/09/2003		☐ Protocol	
Registration date 30/09/2003	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 16/12/2008	Condition category Musculoskeletal Diseases	[] 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

ClinicalTrials.gov (NCT) NCT00176124

Protocol serial number

N/A

Study information

Scientific Title

Acronym

LDAWB2001

Study objectives

Added as of 16/12/2008:

Leukocyte depletion of autologous whole blood prior to storage does not reduce infection rate (wound, urinary tract, other), use of antibiotic treatment and length of hospital stay but may increase retransfusion perioperatively during hip arthroplasty and allogenic transfusion rate.

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

Arthrosis of the hip

Interventions

Autologous blood donation, storage either as leukocyte depleted or undepleted whole blood, retransfusion perioperatively during hip arthroplasty, comparison of infection rate (wound, urinary tract, other), use of antibiotic treatment and length of hospital stay

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Added as of 16/12/2008:

Comparison of infection rate (wound, urinary tract, other), use of antibiotic treatment and length of hospital stay, measured at 90 days

Key secondary outcome(s))

Added as of 16/12/2008:

Blood loss and transfusion rate, measured at 90 days

Completion date

30/04/2005

Eligibility

Key inclusion criteria

Hip arthroplasty patients

Added as of 16/12/2008:

- 1. American Society of Anaesthesiologists (ASA) grade I III
- 2. Aged 18 85 years
- 3. Body weight 50 125 kg
- 4. If female, with either a history of an accepted method of anticonception for at least 3 months prior and 1 month following the termination of the study or climacteric or with a negative betahuman chorionic gonadotropin (B-HCG) test in urine or serum
- 5. Pre-operative blood donation of at least 2 units (450 ml whole blood)
- 6. Pre-operative haemoglobin level greater than 10 mg/dl
- 7. Able and willing to sign informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

Added 16/12/2008:

- 1. Subjects with a contraindication for pre-operative blood donation (PAD)
- 2. Systemic infection
- 3. Acute bacterial or viral diseases
- 4. Anaemia (haemogoblin [Hb] greater than 11 g/dL)
- 5. Myocardial infarction within the past 6 months
- 6. Unstable angina pectoris
- 7. Vascular stenosis (i.e. of the coronary or internal carotid arteries)
- 8. Haemodynamic relevant valvular stenosis
- 9. Heart failure greater than New York Heart Association (NYHA) II
- 10. History of strokes or transient ischaemic attack (TIA)
- 11. Steroid therapy

- 12. Immune deficiency
- 13. Haematological or endocrinological disease
- 14. Coagulopathy
- 15. History of organ transplantation
- 16. Simultaneous participation in a second study
- 17. Pregnancy
- 18. Membership at Jehovah's Witnesses
- 19. Intended use of a cell saver

Date of first enrolment

01/04/2002

Date of final enrolment

30/04/2005

Locations

Countries of recruitment

Germany

Study participating centre Department of Anesthesiology and Critical Care Medicine Mannheim

Germany

67167

Sponsor information

Organisation

University of Heidelberg (Germany)

ROR

https://ror.org/038t36y30

Funder(s)

Funder type

Industry

Funder Name

Auguste Schädler Stiftung, Dannstadt (Germany)

Funder Name

Fresenius Medical Care AG, Bad Homburg (Germany)

Funder Name

Faculty of Clinical Medicine Mannheim, University of Heidelberg (Germany)

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?
Results article	results	01/10/2008		Yes	No