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

Submission date
29/09/2003

Recruitment status
No longer recruiting

Registration date
30/09/2003

Overall study status
Completed

Last Edited
16/12/2008

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

NCT00176124

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Added as of 16/12/2008:
Blood loss and transfusion rate, measured at 90 days

Overall study start date
01/04/2002

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 beta-human 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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

Added October 2008: 1089

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)

Sponsor details
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Faculty of Clinical Medicine Mannheim
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67167

Sponsor type
University/education

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

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	results	01/10/2008		Yes	No