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Randomised, controlled multicentre-trial for the optimised therapy of the acutely ischaemic limb with controlled reperfusion

Submission date 22/03/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/04/2004	**Overall study status** Completed	
Last Edited 31/05/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT00567801

Protocol serial number

S 991228

Study information

Scientific Title
Randomised, controlled multicentre-trial for the optimised therapy of the acutely ischaemic limb with controlled reperfusion

Acronym
CRAIL

Study objectives
Not provided at time of registration

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)
Not Specified

Health condition(s) or problem(s) studied
Acutely ischaemic limb

Interventions
Embolectomy/Thrombectomy vs controlled reperfusion after Embolectomy/Thrombectomy

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Patient >18 years
2. Acute arterial occlusion of one or both lower limbs (Rutherford IIa-III)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Total final enrolment
174

Key exclusion criteria
1. Patients having undergone an attempt at recanalisation (Lyse etc.)
2. Heart failure (New York Heart Association [NYHA] IV)
3. Terminal kidney failure
4. Patients with a known aneurysm of the arteria poplitea

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Germany

Study participating centre
Department of Cardiovascular Surgery
Freiburg
Germany
79106

Sponsor information

Organisation
University Hospital Freiburg (Germany)

ROR
https://ror.org/03vzbgh69

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft, Bonn, Germany

Funder Name
Dr. Köhler-Chemie, Alsbach-Hähnlein, Germany

Funder Name
Local research commission, University hospital Freiburg, 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	01/08/2013	31/05/2019	Yes	No
Other publications	preliminary study	01/10/2005		Yes	No