

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
Registration date 15/04/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/05/2019	Condition category Circulatory System	☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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