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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

NCT00567801

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

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)

Sponsor details

Department of Cardiovascular Surgery University Hospital Freiburg Hugstetterstr.55 Freiburg Germany 79106 +49 761 2702818 beyers@chir.ukl.uni-freiburg.de

Sponsor type

Hospital/treatment centre

Website

http://www.uni-freiburg.de/index_en.php

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

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?
Other publications	preliminary study	01/10/2005		Yes	No
Results article	results	01/08/2013	31/05/2019	Yes	No