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Perioperative management of antiplatelet agents in general and visceral surgery: a pilot study

Submission date 22/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/11/2009	**Overall study status** Completed	
Last Edited 25/10/2022	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
S-003/2008

Study information

Scientific Title
Pilot phase of a randomised controlled trial to optimise the perioperative management of antiplatelet agents in the field of general and visceral surgery

Study objectives
Surgery with perioperative continuation of antiplatelet agents can be safely performed without an increase of complication rates and potential decrease of thromboembolic events.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Heidelberg approved on the 25th February 2008 (ref: S-003/2008)

Study design
Pilot two-armed block randomisation clinical controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgical complication rates, thromboembolic events

Interventions
In the pilot phase, we provide low-risk patients with acetylsalicylic acid (ASA) 100 mg/day. There are two arms of randomisation: discontinuation versus continuation of aspirin. Patients stop 5 days before operation and start on the 5th post-operative day again (if randomised to discontinuation) or continue the intake of aspirin. Follow-up is 30 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Acetylsalicylic acid (aspirin)

Primary outcome(s)
1. Bleeding complications
2. Thromboembolic events

Key secondary outcome(s))
1. Duration of surgery
2. Blood loss during surgery
3. Complication rate
4. Length of hospital stay
5. Readmission to hospital after discharge
6. Difference between laparoscopic versus open surgery

Completion date
20/12/2009

Eligibility

Key inclusion criteria
1. Cardiac low and medium risk patients with antiplatelet agents
2. Informed consent
3. Aged over 18 years, either sex
4. Physical and psycological ability to participate in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Cardiac high risk patients
2. Psychiatric disorder
3. No informed consent

Date of first enrolment
01/01/2009

Date of final enrolment
20/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
Im Neuenheimer Feld 110
Heidelberg
Germany
69120

Sponsor information

Organisation
University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany) - Surgical Clinical Study Centre

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/02/2012		Yes	No
Protocol article	protocol	03/03/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes