

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 ☒ Protocol
Registration date 03/11/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/10/2022	Condition category Other	☐ 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

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)

Primary study design

Interventional

Study design

Pilot two-armed block randomisation clinical controlled trial

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 psychological 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