

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

<b>Submission date</b> 22/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/10/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Juergen Weitz

**Contact details**  
Im Neuenheimer Feld 110  
Heidelberg  
Germany  
69120  
+49 (0)6221 56 6110  
juergen.weitz@med.uni-heidelberg.de

## 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 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?
<a href="#">Results article</a>		01/02/2012		Yes	No
<a href="#">Protocol article</a>	protocol	03/03/2011		Yes	No