

Efficacy and tolerability of physostigmine salicylate for treatment of post-operative delirium after aortocoronary-bypass operation (ACVB): a prospective, double-blind, placebo-controlled, two parallel-groups, phase III study

Submission date 17/10/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 28/11/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/08/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Markus Verch

Contact details
Department of Cardiosurgery
Clinic for Surgery
University Hospital Heidelberg
Heidelberg
Germany
69120

Additional identifiers

Protocol serial number
AM-KS-III/06/08

Study information

Scientific Title

Study objectives

Physostigmine salicylate increases the probability to recover from a post-operative delirium 30 minutes after its administration assessed by use of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) test compared to placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Prospective, randomised, double-blind, placebo-controlled, parallel-group, phase III study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Delirium during post-operative arousal

Interventions

Single administration of physostigmine salicylate 0.03 mg per kg body weight (b.w.) administered intravenously versus placebo.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Physostigmine salicylate

Primary outcome(s)

Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) test, assessed 30 minutes after the administration of IMP.

Key secondary outcome(s)

1. Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) test, assessed 120 minutes after administration of IMP
2. Serumenticholinergic Activity (SAA) assessed 60 minutes after administration of IMP
3. Richmond Agitation and Sedation Scales (RASS), assessed 30 and 120 minutes after administration of IMP
4. Adverse events up to 120 minutes after administration of IMP

5. Vital signs (blood pressure, heart rate, filling pressures and oxygen saturation) documented 10, 20, 30, 60 and 120 minutes after administration of IMP

Completion date

01/12/2009

Eligibility

Key inclusion criteria

1. Both males and females, aged greater than or equal to 18 and less than 90 years
2. Informed consent
3. Indication for an elective ACVB under mild hypothermia (34°C)
4. Negative pregnancy test in females of childbearing potential
5. Ability of subjects to understand the nature of the study
6. Delirium during the post-operative arousal

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Known neurologic deficits
2. Arterial occlusive disease (AOD), grade IIb
3. Glaucoma with retinal damage
4. Asthma or chronic obstructive pulmonary disease (COPD) (forced expiratory volume in 1 second [FEV1] less than 70%)
5. Acute bleeding
6. Acute renal insufficiency
7. Use of a circulation support system
8. Body weight greater than 130 kg
9. Concurrent participation in another interventional trial
10. Concurrent treatment of cerebral dysfunction or cerebral circulatory disorders
11. Known intolerability/hypersensitivity to the investigational medicinal product (IMP) or applied pharmaceutical ingredients or other remedies with similar chemical structure

Date of first enrolment

01/12/2008

Date of final enrolment

01/12/2009

Locations

Countries of recruitment

Germany

Study participating centre

Department of Cardiosurgery

Heidelberg

Germany

69120

Sponsor information

Organisation

Dr. Franz Köhler Chemie GmbH (Germany)

ROR

<https://ror.org/036ezxy46>

Funder(s)

Funder type

Industry

Funder Name

Dr. Franz Köhler Chemie GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration