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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	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/11/2008	**Overall study status** Completed	
Last Edited 30/08/2011	**Condition category** Mental and Behavioural Disorders	

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
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

Primary study design
Interventional

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

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. Serumanticholinergic 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