Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit

From 2013-12-01 to 2018-11-30, closed project

Objective

The majority of critically ill children admitted to Paediatric Intensive Care Units (PICU) will require sedation and analgesia which is commonly achieved with a combination of a benzodiazepine and an opioid. However, these agents have a significant side-effect profile, including tolerance, withdrawal and respiratory/circulatory depression. Clonidine is commonly used for sedation in PICU and recommended by guidelines in various countries although there is a lack of evidence regarding it safety and efficacy in this setting. The need for safety and efficacy data as well as an age appropriate formulation for clonidine has been realised and clonidine is included in the EMA “Revised Priority List for Studies into Off-patent Medicinal Products”. Thus this proposal addresses an important paediatric therapeutic need. It is designed to fulfill the requirements for most ethical research in the paediatric population considering risk minimisation for patients, avoiding unnecessary studies and make use of already available data as outlined in the Paediatric Regulation (EC) No 1901/2006. The objectives of this project are a) to develop an age appropriate formulation of clonidine suitable for sedation of children in PICU b) to conduct a randomised, phase III, double-blind, active-controlled parallel group clinical trial of clonidine vs midazolam in patients from birth to 18 years to establish the efficacy and safety, including long-term outcomes and dose-dependent effects of clonidine and c) to establish an European consensus guideline for sedation of critically ill children. The ultimate goal is to use these data and to apply for a PUMA. On this basis a Paediatric Investigation Plan (PIP) has been approved by the EMA in February 2013 and is reflected in the work plan of CloSed. The project will increase the availability of paediatric medicines, foster the conduct of clinical trials in children and establish international paediatric research collaborations.

Related information

Report Summaries

Final Report Summary - CLOSED (Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit)
Coordinator

UNIVERSITATSKLINIKUM ERLANGEN
MAXIMILIANSPLATZ 2
91054 ERLANGEN
Germany
EU contribution: EUR 1 428 894,80

Activity type: Higher or Secondary Education Establishments

Administrative contact: Katrin Faber
Tel.: +49 9131 8535902
Fax: +49 9131 8535903

Contact the organisation

Participants

UNIVERSITY COLLEGE LONDON
GOWER STREET
WC1E 6BT London
United Kingdom
EU contribution: EUR 587 368,20

Activity type: Other

Administrative contact: Kamila Kolasinska
Tel.: +44 20 31083033
Fax: +44 20 31083096

Contact the organisation

Therakind Ltd
DOLLIS PARK ROAD WINSTON HOUSE 2
NE 1HF London
United Kingdom
EU contribution: EUR 1 917 800

Activity type: Private for-profit entities (excluding Higher or Secondary Education Establishments)

Administrative contact: Louise Rawcliffe
Tel.: +44 20 8346 6035

Contact the organisation

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM
DR MOLEWATERPLEIN 40
3015 GD ROTTERDAM
Netherlands
EU contribution: EUR 776 600

Activity type: Higher or Secondary Education Establishments

Administrative contact: Ellen Schenk
Tel.: +31107044876

Contact the organisation
FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS
VIA ABATE EUSTASIO 30
70010 VALENZANO BARI
Italy
EU contribution: EUR 352 340

Activity type: Research Organisations
Administrative contact: Fedele Bonifazi
Tel.: +39 080 4670430
Fax: +39 080 4670281
Contact the organisation

KAROLINSKA INSTITUTET
Nobels Vag 5
17177 STOCKHOLM
Sweden
EU contribution: EUR 381 700

Activity type: Higher or Secondary Education Establishments
Administrative contact: Eva Gipperth
Tel.: +46 852487199
Fax: +46 8304613
Contact the organisation

TARTU ULIKOOL
ULIKOOLI 18
51005 TARTU
Estonia
EU contribution: EUR 180 975

Activity type: Higher or Secondary Education Establishments
Administrative contact: Tuuli Metsvaht
Tel.: +372 7319550
Fax: +372 7319503
Contact the organisation

UNIVERZITA KARLOVA
OVOCNY TRH 560/5
116 36 PRAHA 1
Czechia
EU contribution: EUR 166 750

Activity type: Higher or Secondary Education Establishments
Administrative contact: Kristyna Matejkova
Tel.: +420 224964264
Fax: +420 224964163
Contact the organisation
VERENIGING SAMENWERKENDE OUDER- EN PATIENTENORGANISATIES
Vredehofstraat 31
3761HA SOEST
Netherlands

See on map

**Activity type:** Public bodies (excluding Research Organisations and Secondary or Higher Education Establishments)

**Administrative contact:** Cor Oosterwijk
Tel.: +31 356034040

Contact the organisation

OSPEDALE PEDIATRICO BAMBINO GESU
PIAZZA SANT ONOFRIO 4
00165 ROMA
Italy

**EU contribution:** EUR 96 976,75

See on map

**Activity type:** Other

**Administrative contact:** Sonya Jane Martin
Tel.: +39 06 6859 2497
Fax: +39 06 6859 2101

Contact the organisation

Last updated on 2017-03-22
Retrieved on 2019-08-30

© European Union, 2019