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Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit



CloSed Project

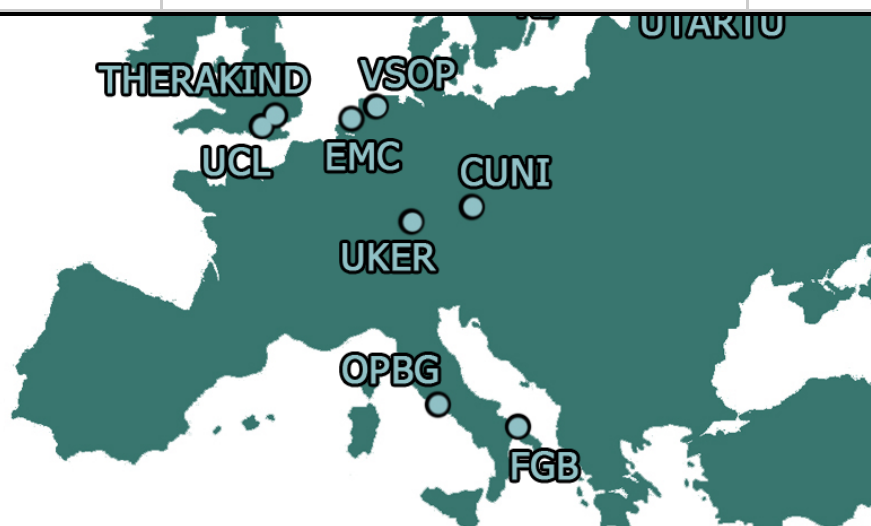
Improving sedation of children in critical care

Welcome to the sixth Newsletter of the 5-year project CloSed, funded by the European Union and aimed to improve patients' treatment in the intensive care setting by studying clonidine.

CloSed is developing a **new formulation of clonidine**, specifically designed for children, and conducting a clinical trial in patients under the age of 18 with the aims to generate **safety and efficacy** data on clonidine in children, to support the **Paediatric Use Marketing Authorisation (PUMA)** application and to develop **guidelines for sedation** of critically ill newborns and children in the Paediatric Intensive Care Unit (PICU). Throughout the project, the health of children will be of utmost priority and all research activities will be conducted in accordance with European ethical requirements for studies involving the paediatric population.

Project Consortium

The project Consortium comprises 10 European partners: one not-for-profit organisation, five clinical centres, one SME, two universities and one patient organisation, all focused on developing appropriate medicines for children.

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Update on the CLON01 study

One of the key elements of the CloSed project is the study CLON01 ([EudraCT Number: 2014-003582-24](#) [ClinicalTrials.gov Identifier: NCT02509273](#)).

After having received full authorisation from the national Competent Authorities and local Ethics Committees in the Netherlands and Germany, two study sites are presently open for recruitment: Erasmus Universitair Medisch Centrum Rotterdam and the Department of Paediatrics and Adolescent Medicine at the Universitaetsklinikum Erlangen.

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What's new?

Site Initiation Visit at Ospedale Pediatrico Bambino Gesù (Rome, Italy)

On October 10th-11th, 2016, the site initiation visit (SIV) was held at Ospedale Pediatrico Bambino Gesù (OPBG) in Italy. The visit's programme stretched over two days, during which all site documentation was reviewed and the study details were presented with particular reference to study background, patient population, the Investigational Medicinal Products and study protocol features.

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CloSed publication in Journal of Pharmacy and Pharmacology

A mini-review of non-parenteral clonidine preparations for paediatric sedation has recently been published in the Journal of Pharmacy and Pharmacology by Dr. Sara Hanning and

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Information for lay people

An informative leaflet illustrating CloSed using more direct and generally understandable language is available in English in order to raise awareness about the project to the non-scientific public.

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Support information for patient families

A summary information for parents was developed under the guidance of the patient organisation VSOP (Vereniging Samenwerkende Ouder – en Patiëntenorganisaties). Adapted to local language, this summary information can be offered to parents in addition to the Patient Information Sheets in order to support recruitment and to ease communication with patients and their families.

Recent Events

March 20th-21st 2017

Erlangen

CloSed General Assembly Meeting #3

The last General Assembly Meeting of the CloSed Consortium has been held on March 20th to 21st in Erlangen, Germany. During the two meeting days, the Consortium has discussed the experiences and challenges of patient recruitment and reviewed the project's overall progress.

October 21st, 2016

Geneva

First Investigator Meeting in Geneva (Switzerland)

On October 21st, 2016 the first Investigator Meeting of the CloSed project took place in Geneva (Switzerland). The meeting was aimed to bring all principal investigators of the CLON01 study together to discuss practical clinical aspects of the CloSed trial and to discuss how to improve recruitment.

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