



Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit



Newsletter #2

CloSed Project Improving sedation of children in critical care

CloSed is a 5-year project funded under the Seventh Framework Programme (FP7) with an international Consortium comprising 10 European partners and coordinated by the University Hospital of Erlangen.

The project aims to study clonidine, which is currently used off-label as sedative in paediatric intensive care units (PICU) and to conduct a **multicentre clinical trial in children until the age of 18**.

Indeed, children in critical care, admitted to the intensive care unit and in need of sedation, are often treated with drugs that are not specifically approved for them. Thus, **age-appropriate formulations and data on efficacy and safety are required for this drug**. CloSed project is expected to fill this gap, since it is aimed to develop and test a parenteral age-appropriate formulation of clonidine, specifically for the treatment of neonate, paediatric and adolescent patients. Once it will be demonstrated its efficacy and safety, the project results will be used to obtain a Paediatric Use Marketing Authorisation (PUMA).

[Read more](#)

Project Consortium

The project Consortium comprises 10 European partners: one scientific research organisation, five clinical centres, one SME, two universities and one patient organisation, all focused on developing appropriate medicines for children.



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Survey on local practices

In the course of the preparation for the CloSed study, a survey was conducted to examine the current local practices in the use of sedation and pain treatment at the five CloSed study centres (University Hospital Erlangen - Germany, Erasmus Universitair Medisch Centrum Rotterdam - The Netherlands, Karolinska Institutet - Sweden, Charles University in Prague - Czech Republic, Ospedale Pediatrico Bambino Gesù - Italy).

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Training and implementation of the sedation and comfort scores

One important activity of the CloSed study is the training of medical staff in order to provide the knowledge to obtain the outcome measures defined in the Clinical Study Protocol. To this aim, the following validated scoring systems have been trained: COMFORT behaviour scale (COMFORT-B scale), Numeric Rating Scale (NRS) and Nurse Interpretation of Sedation Score (NISS).

[Read More](#)

Events

November 11, 2014

London

CloSed General Assembly Meeting

The General Assembly Meeting of the CloSed project took place in London, England on November 11th, 2014 and was organised by Therakind and University College London (UCL). The meeting focused on the summary of main achievements of the first year and the discussion of next steps and timelines in the CloSed Project.

[Read more](#)

October 3, 2014

Castellaneta M.

CloSed at the first TEDDY General Assembly

On October 3rd, 2014, the first TEDDY NETWORK General Assembly was held in Castellaneta Marina (Taranto, Italy). The initiative was part of the seventh edition of the Foresight Training Course, organised by the [Gianni Benzi Pharmacological Research Foundation](#), a short intensive course devoted to create a critical mass of expertise in the different areas of Regulatory Sciences.

[Read more](#)

Partner: Focus On



Patient association

Vereniging Samenwerkende Ouder - en Patiëntenorganisaties (VSOP) is the Dutch national patient umbrella organisation for rare and genetic disorders and represents about 70 disease-specific patient and parent organizations in The Netherlands. Its mission is to optimise the implications of research in the field of genetics, medical biotechnology and life sciences for the well-being and health of patients, as well as all other citizens.

One of VSOP's focuses concerns therapy development for rare and paediatric disorders and the involvement of patients and their organisations therein.

In the CloSed project, VSOP represents the European patient organisation EGAN, which is a European network of patient organisations for serious diseases, focussing on research (policy) and therapy development (www.egan.eu and www.biomedinvo4all.com).

VSOP connects the clinical/scientific work of the project with the European patient perspective, i.e. by setting up and maintaining a Patient Advisory Board (PAB) and advising on ethical and communication issues from a European patient perspective.

[Partner's website](#)



Private company (SME)

Therakind is a private European pharmaceutical company established in 2006 and dedicated to create, develop and improve paediatric medicines. The company's primary objective is to increase the availability of authorised paediatric medicines and to ensure that the medication used today is both, safe and effective. Therakind has considerable experience in drug evaluation, formulation, clinical and regulatory strategies and management, ensuring an optimal clinical programme whilst avoiding unnecessary paediatric trials, obtaining scientific advice, securing agreements for Paediatric Investigation Plans (PIPs) and approvals for clinical trial and marketing authorisations.

In CloSed, Therakind oversees all regulatory activities relating to the PIP and PUMA application and is responsible for the preparation and submission of the PUMA. Therakind is also responsible for the Study Management, the Monitoring and Quality Assurance of the clinical trial.

[Partner's website](#)

What's new

CloSed project leaflets

The CloSed project leaflets are going to be released soon and will be published in two different versions:

- A scientific leaflet targeting a specialised audience
- A layman's leaflet targeting patients, parents and patient associations

Stay connected with the CloSed project to be updated!

CloSed featured on HealthCompetence, EGAN and Cordis websites

A dedicated page to the CloSed project was published on [HealthCompetence](#) and [EGAN](#) website.

Additionally, the CloSed Kick-off Meeting press release entitled "EU FP7 "CloSed - Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit" Project Kick-off Meeting", was published on the [CORDIS](#) (Community Research and Development Information Services) website.

[Read more](#)

CloSed has created its own official Facebook page!

By exploiting this very useful two-way communication form of media, all project activities and results can be shared more quickly with a wide public audience while anyone interested in the project has the opportunity to contact the CloSed partners directly.

Visit us on [Facebook](#)! Stay connected!

The CloSed Consortium wishes all of you a Merry Christmas and a Happy New Year!

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Website



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