



Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit



CloSed Project

Improving sedation of children in critical care

Welcome to the seventh 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 twelve European partners and other four study sites: one not-for-profit organisation, ten clinical centres, one SME, two universities and one patient organisation, all focused on developing appropriate medicines for children.



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RECENT EVENTS

Nov 23, 2017
LONDON

CloSed Investigator Meeting #2 London

The second investigator meeting took place at UCL School of Pharmacy in London on November 23rd 2017. Principal investigators of the CloSed study shared their experiences from first patients and a third clinical protocol amendment was discussed.

[Read more](#)

WHAT'S NEW?

Site Initiation Visit at Prague

Dec 5, 2017

On December 5th 2017, the Site Initiation Visit (SIV) was carried out at the Czech study site, the University Hospital of Charles University in Prague. The site received the investigational medicinal products and is about to start screening.

[Read more](#)

Site Initiation Visit at Tallinn Children`s Hospital

Oct 20, 2017

On October 30th 2017, the Site Initiation Visit (SIV) was carried out in Tallinn at the Tallinn Children's Hospital. The site's highly motivated study team has started screening and recruitment shortly after.

[Read more](#)

Tallinn Children`s Hospital becomes a new trial site

Jul 20, 2017

The University of Tartu (UTARTU) with its Tallinn Children`s Hospital joined the randomised trial as a recruiting site. UTARTU is one of the CloSed Project Beneficiaries and has primarily been in charge of coordinating the medical-ethical issues in accordance with ICH guidelines and GCP and developing a validated method for sample preparation and analysis.

[Read more](#)

Study protocol publication in BMJ Open Journal

Jun 21, 2017

The study protocol has been published online in the BMJ Open Journal on June 21st 2017.

The paper provides an overview of the study protocol: the trial aims, the methods used and the analysis foreseen, as well as the ethical considerations of such a paediatric multi-national trial.

[Read more](#)

Site Initiation Visit at Karolinska Institutet

children's hospital (Stockholm)

June 14, 2017

On June 14th 2017, the Site Initiation Visit (SIV) was held at the new building of Karolinska Institute children's hospital (KI) in Stockholm.

After visiting the site facilities, the SIV was concluded successfully. The highly motivated team at KI is now awaiting the IMP to be shipped to the site, before recruitment can start.

[Read more](#)

PARTNERS AND STUDY SITES: FOCUS ON



Cnopf'sche Paediatric Clinic

The Diakonie Neuendettelsau – Cnopf'sche Kinderklinik Nürnberg is one of the most traditional clinics for children and adolescents in Germany.

The hospital and UKER have a long history of collaboration for improving patient care in the field of neonatal care and it now operates as a new recruiting site in the CloSed trial.

Website: <https://www.diakonieneuendettelsau.de/>

[Read more](#)



Hospital Universitario 12 de Octubre

The Hospital 12 de Octubre is a tertiary public hospital, part of Madrid Regional Health Service (SERMAS). The clinical teams participate in European projects and paediatric clinical studies, also acting as national coordinator. Three departments "Mother and Child" cover the full range of paediatric intensive care: the neonatal intensive care unit, the paediatric intensive care unit and the post-anaesthesia critical care unit.

Website: http://www.madrid.org/cs/Satellite?pagename=Hospital12Octubre/Page/H12O_home

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Civico Di Cristina Benfratelli
Azienda di Rilievo Nazionale ad Alta Specializzazione

Azienda Ospedaliera di Rilievo Nazionale e di Alta Specializzazione Civico, Di Cristina, Benfratelli (ARNAS-Civico).

The Azienda Ospedaliera di Rilievo Nazionale e di Alta Specializzazione Civico Di Cristina Benfratelli (ARNAS-Civico) based in Palermo is the reference centre for the management of high risk pregnancies and of the newborns at high risk of morbidity and mortality in western Sicily. The Neonatal Intensive Care Unit (NICU) and Neonatology is a new recruiting site for neonatal patients for the randomised trial.

Website: <http://www.arnascivico.it/>

[Read more](#)



Azienda Ospedaliera Universitaria Consorziale Policlinico Giovanni XXIII

The Azienda Ospedaliera Universitaria Consorziale Policlinico Giovanni XXIII of Bari is a recognised clinical centre encompassing paediatric and non-paediatric expertise in different therapeutic areas in Apulia, Italy. It is currently involved in several multicentre and multinational paediatric research activities and has now joined the CloSed study to recruit neonates.

Website: <https://www.sanita.puglia.it/web/ospedalegiovannixxiii>

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