POLICLINICO DI SANT'ORSOLA

Dipartimento della Donna, del bambino e delle malattie urologiche
Unità Operativa Anestesiologia e Rianimazione

To the kind attention of:

EudraCT team
European Medicines Agency

Subject: End of Trial: prematurely ended due to futility

TITLE: **Efficacy and Safety of Dexmedetomidine during weaning from analgesia and sedation in Pediatric Intensive Care Unit. A multicenter, double-blind, randomized controlled trial.**

UNIQUE PROTOCOL ID: **EudraCT 2015-002124-80 OsSC**

SECONDARY IDs: **TIP-15-01**

ETHICAL COMMITTEE APPROVAL NUMBER: CE 167/2016/O/Sper

SPONSOR: Azienda Ospedaliero-Universitaria di Bologna IRCCS Policlinico di Sant'Orsola

PRINCIPAL INVESTIGATOR: Maria Cristina Mondardini, MD - Azienda Ospedaliero-Universitaria di Bologna IRCCS Policlinico di Sant'Orsola, Pad 13 Via Albertoni 15 – 40138 Bologna, Italy. Phone: +390512143650. Email: mariacristina.mondardini@aosp.bo.it

On 03/28/2020, after analyzing the interim analysis results, the study coordinator, in agreement with the Data and Safety Monitoring Board (DSMB), decided to prematurely interrupt the study. The decision to interrupt the study is due to futility.

The sample size calculation of the Trial was computed using an adaptive approach based on a two-stage Group Sequential Design with an interim sample size reassessment. After reaching the sample size for the interim analysis (i.e. n=40 patients enrolled who completed the study), the treatment efficacy was evaluated in the Intent-to-Treat (ITT) population using the Z test statistics in order to compare the prevalence of Withdrawal Syndrome (primary outcome measure) between the two treatment groups. The conditional power (CP) was found to be 0.25, i.e. lower than 0.3, which required a sample size reassessment. A sample size re-estimation assessment was equal to 308 patients. The DSMB was therefore consulted and a decision was made to early terminate the trial for futility reasons.

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Study Start: August 30, 2018
Primary Completion: January 18, 2020
Study Completion: January 18, 2020

The Principal Investigator attaches the results of the interim analysis of the Trial published in the indexed journal Pharmacotherapy.

Maria Cristina Mondardini MD
Principal Investigator

Bologna, 09/10/2022

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