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ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

Dipartimento per la gestione integrata del rischio infettivo
Malattie infettive UOC

Bologna, 27/01/2025

Subject: Premature termination of the trial "BDG-ETHIC"

Full title of the trial: *"A β-d-glucan driven antifungal stewardship approach to manage empirical therapy in patients at very high risk for invasive candidiasis: a randomized controlled trial"*
Sponsor protocol code: BDG-ETHIC
EudraCT Number: 2015-001566-26
Ethics Committe approval code: 222/2016/O/Sper
Ethics Committe approval date: 17/01/2017
Sponsor: IRCCS Azienda Ospedaliero-Universitaria di Bologna, Policlinico Sant'Orsola
Scientific responsible: Prof. Pierluigi Viale
Clinical center: IRCCS Azienda Ospedaliero-Universitaria di Bologna, Policlinico Sant'Orsola, Infectious Diseases Unit

We hereby inform you of the premature termination of the above-mentioned clinical trial on December 31, 2019, due to the initiation of a concurrent trial involving the same study population (patients with complicated abdominal surgical pathology and severe sepsis/septic shock).

Final status of the study:

- Actual recruitment start date: 24/02/2017
- Last Patient First Visit (LPFV): 12/03/2019
- Last Patient Last Visit (LPLV): 10/06/2019
- Actual number of subjects enrolled in the trial: 34 (Italy)
    - Arm 1 (experimental): 17
    - Arm 2 (standard): 17

Age Distribution of Subjects:

Age group	**Arm 1** Number of subjects	**Arm 2** Number of subjects	**TOTAL**
In Utero	0	0	0
Preterm newborns (< 37 weeks)	0	0	0
Newborns (0-27days)	0	0	0
Infants and toddlers (28days – 23months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 year)	0	0	0
From 18 - 64 years	8	6	14
From 65 - 84 years	8	10	18
Over 85 years	1	1	2

Gender Distribution of Subjects:

Gender	**Arm 1** Number of subjects	**Arm 2** Number of subjects	**TOTAL**
Female	5	6	11
Male	12	11	23

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- Adverse events: no adverse events were reported during the trial

The investigational drug was prescribed according to its authorized therapeutic indications. The intervention in the experimental arm (Arm 1) consisted of the potential suspension of antifungal therapy based on serum beta-D-glucan (BDG) levels. At the time of the study's premature termination, all enrolled patients had completed therapy with the investigational drug.

The study aimed to evaluate the role of beta-D-glucan (BDG) as a stewardship tool for managing antifungal therapy in patients with complicated abdominal surgical pathology and severe sepsis/septic shock. The hypothesis posited that antifungal therapy management based on serial BDG measurements could reduce antifungal therapy consumption without negatively affecting clinical outcomes such as mortality and length of stay in the intensive care unit.

Unfortunately, the premature termination of the trial resulted in an insufficient sample size, preventing a meaningful analysis of the data.

Kind regards

Prof. Pierluigi Viale
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