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ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

Dipartimento Ospedale della donna e del bambino

Ostetricia e medicina dell'età prenatale UOC

Bologna, June 16, 2022

Subject: clinical trial: *Effetti della somministrazione di espansori del volume plasmatico materno in gravidanze complicate da restrizione della crescita fet*ale (Effects of the administration of maternal plasma expanders in pregnanciescomplicated by fetalgrowthrestriction) internal code 016/2012/O/Sper, EudraCT 2011-003730-13

Dear EudraCT team,

I am writing on behalf of Prof. Tullio Ghi, who is now working in a different university, and has been the principal investigator of the above trial, that was initiated and immediately interrupted in our unit in 2012. The first patient was enrolled into the study group and according to the research protocol received serial infusions of hydroxyethyl starch. The outcome of pregnancy was good, and an healthy neonate was delivered. However, the pathological examination revealed an unusual accumulation of vacuoles into the placenta. Similar findings had been identified in the placenta of another patient that had been delivered in our hospital in the same period and was not a part of the study but had received the same plasma expander for a different indication.
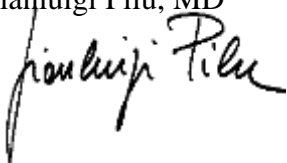
A correlation between administration of hydroxyethyl starch and placental modification was suspected. Given the extent of the pathological findings, the study was immediately interrupted and no other patient received the drug (October 2012). A formal report was addressed to AIFA, the Italian drugs regulatory agency. Eventually, AIFA revoked the authorization to use plasma expanders containing hydroxyethyl starch for any indication. At that time the hospital and local Ethical Committee were informed that the trial had been terminated

I would be delighted to provide any further information where necessary,

I remain with the best regards,

Sincerely,

Gianluigi Pilu, MD

Professor of Obstetrics and Gynecology
Head of Obstetrics
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