COMMISSIE MEDISCHE ETHIEK
UZ KU Leuven
UZ Gasthuisberg
Herestraat 49
B 3000 Leuven (Belgium)

Leuven, 22 October 2015

Prof. dr. Liesbeth Lewi
GYNAECOLOGIE-VERLOSKUNDE

Identification mark:	**EudraCT-nr:**	**Belg. Regnr:**
S58224		B322201525345

Early versus late intervention for twin reversed arterial perfusion sequence: an open-label randomized controlled trial.

FINAL FAVOURABLE ADVICE (Cfr Favourable advice dd 17 August 2015)

Dear colleague

The Committee 'Commissie Medische Ethiek van de Universitaire Ziekenhuizen KU Leuven' has examined and discussed the above mentioned dossier during her meeting of 5 august 2015.

After examining the additional information and/or adapted documents the Committee has considered this study, as described in the protocol, as scientifically relevant and ethically justified. Therefore, the Committee gives her approval on this study.

For the assessment of this dossier, documents submitted on 22 July 2015, have been taken into account.

The favourable advice concerns:

Protocol:
versie 1.0 van 12/7/2015

Information form and informed consent form:
aangepast ICF versie 10 augustus 2015 Nl +F

The Committee confirms working in accordance to the ICH-GCP principles (International Conference on Harmonization Guidelines on Good Clinical Practice), with the latest version of the Declaration of Helsinki and applicable laws and regulations.

The Committee confirms that - in case of conflict of interest - involved members do not take part in the vote concerning the study.

List of members: see appendix.

Points of concern: (if applicable)

The sponsor is responsible for the conformity of the documents in other languages with the Dutch documents.

Provided that there is a **Clinical Trial Agreement**, the study can only be conducted if the Clinical Trial Agreement has been approved and signed by the managing director of UZ Leuven (and/or by an authorized representative of KU Leuven R&D).

Studies on drugs and/or "medical devices" should be reported by the client (PI or sponsor) to the FAMHP (Federal Agency for Medicines and Health Products).
Studies involving drugs are only allowed to be undertaken, provided that the minister (FAMHP) does not state objections within legal deadlines as described in art. 13 of the Belgian law of 7/5/2004 concerning experiments on human subjects.
Certain studies using medical devices are also covered by legal deadlines (KB of 17/3/2009). Please consult the FAMHP website for more information: www.fagg-afmps.be.

The research on embryos in vitro is covered by the law of May 11, 2003. Before the research project can start, such research also requires a positive advice of the Federal Committee for medical and scientific research on embryos in vitro.

Please take into account the regulations of the hospital concerning tissue management and the regulations of the law of December 19, 2008.

This favourable advice of the Committee does not imply that she will take responsibility for the planned study. You will remain responsible for the study. In addition, you should ensure that your opinion as an involved researcher is reproduced in publications, reports for the government, etc. which are the result of this study. You are reminded that concerning clinical studies, any observed serious event needs to be reported immediately to the sponsor and the medical ethical committee, even if the causal relationship with the study is unclear.

We request you to inform us if the study will not be initiated, or when it will be closed or prematurely interrupted (stating the reason).

*If the study is not terminated within a year, the ICH-GCP demands that an **annual progress report** will be provided to the Committee.*

*Finally, we request you to report the termination (early or planned) of the study within the legal deadlines and provide the **Clinical Study Report** to the Committee.*

Yours sincerely,

Prof. Dr Walter VAN DEN BOGAERT
Voorzitter Commissie Medische Ethiek
UZ K.U.LEUVEN

Prof. dr W. Van den Bogaert
Chairman
Commissie Medische Ethiek UZ KU Leuven

Cc:
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List of members Commissie Medische Ethiek UZ KU Leuven on 5 August 2015 (date of the last review of this study):

Chairman	prof. dr. em. Walter Van den Bogaert	Radiotherapy-Oncology
Vice-chairman	prof. dr. em. Guido Verhoeven	Experimental Medicine
Secretary	dr. Sabine Graux	Physician
Secretary	dr. Sonja Haesendonck	Physician
	mr. Karel Op de Beeck	Head Nurse
	mrs. Christine Mathieu	Medical Legislation
	dr. José Thomas	Medical Oncology
	dr. Lut De Groote	General Practitioner
	prof. Ben Van Calster	Statistics
	prof. J.R. Thomas	Clinical Pharmacology
	prof. dr. Dominique Bullens	Paediatrics
	prof. dr. Jan Van Hemelrijck	Anesthesiology
	prof. dr. Jan de Hoon	Clinical Pharmacology
	prof. dr. Xavier Bossuyt	Immunology
	prof. dr. em. Ivo De Wever	Surgical Oncology
	prof. dr. em. Raymond Verhaeghe	Cardiology
	prof. dr. em. Willem Daenen	Cardiac Surgery

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