Leuven, 17 Mar 2022

Ethics Committee
Research UZ/KU Leuven
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prof. dr. Karin Haustermans
RADIOTHERAPIE

Our reference:	EudraCT-nr:	Belg. Regnr:
S64706		B3222021000687

Health Effects of CArdiac FluoRoscopy and MOderN Radlotherapy in PediatriCs–Radiotherapy.

Positive advice in accordance with the law of 7 May 2004 on experiments on the human person

Dear colleague

The Ethics Committee Research (EC Research) of University Hospitals Leuven (UZ Leuven) has examined and discussed the above mentioned dossier at its meeting of 29 Nov 2021.

After having consulted the additional information and/or adapted documents relating to this dossier, EC Research considers that the proposed study, as described in the protocol, is scientifically relevant and ethically justified. It therefore gives on 17 Mar 2022 a favourable opinion of this study.

EC Research emphasizes the responsibility of the PI/promotor of this study concerning the privacy of the person/patient data in contacts with patients, or when viewing patient data, including the correct implementation thereof by coworkers and students. The PI/promotor is responsible for the implementation of the project proposal in accordance with applicable laws and regulations including, but not limited to, the EU regulation 2016/679 (General Data Protection Regulation), the Belgian Law on patients' rights of 22/8/2002, and the policy of the institution where the research will be carried out.

EC Research refers to the ICH/GCP guidelines on its website, and confirms that a GCP-training is required from each investigator. It is the responsibility of the principal investigator that each member of the study team has a valid GCP-certificate.

For the assessment of this dossier, documents/answers submitted on 18 Nov 2021, 20

Jan 2022, 08 Mar 2022 and 16 Mar 2022 have been taken into account.

The favourable advice concerns:

Protocol:

Version 3.0 dd 31Aug2020

Informed Consent Form:

ICF version (ouders) 4.1 dd 25 januari 2022 Nl + Fr
Informed Assent formulier version (minderjarigen) 4.1 dd 25 januari 2022 Nl + Fr
Informed Assent formulier version (adolescenten) 4.1 dd 25 januari 2022 Nl + Fr Informed Assent formulier version (pre-adolescenten) 4.1 dd 25 januari 2022 Nl + Fr
ICF (volwassenen) 4.1 dd 25 januari 2022 Nl + Fr
ICF (Deelnemers die volwassen geworden zijn) 4.1 dd 25 januari 2022 Nl + Fr

Other subject information documentation:

Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_INCL_13TO17 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_INCL_8TO12 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_INCL_5TO7 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_INCL_2TO4 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_YA_M12 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_YA_M0 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_M12_13TO17 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_M12_8TO12 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_M12_5TO7 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_M12_2TO4 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_M0_13TO17 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_M0_8TO12 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_M0_5T07 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_PAR_M0_2TO4 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_CHILD_13TO17 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_CHILD_8TO12 Nl + Fr
Vragenlijst over de kwaliteit van het leven HARMONIC_CHILD_5TO7 Nl + Fr

(received 08 Mar 2022)

Proof of "no-fault" insurance cover:

dd 30Jun2020 (duration: 01Sep2020 - 01Sep2027)

GDPR questionnaire:

Submitted on 25Nov2020

EC Research confirms working in accordance with the ICH-GCP principles (International Conference on Harmonization Guidelines on Good Clinical Practice), the latest version of the Declaration of Helsinki, the Oviedo Convention on Human Rights and Biomedicine and applicable laws and regulations.

EC Research 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 conformity of translated documents compared to the Dutch documents, is the responsibility of the sponsor.

We would like to draw your attention to the fact that EC Research expects her initial

comments to be taken into account ab initio at the next submission by the same sponsor.

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

Studies with investigational medicinal products and certain studies with "medical devices" should be submitted by the client (PI or sponsor) to the FAMHP (Federal Agency for Medicines and Health Products).

Studies with investigational medicinal products are only allowed to be conducted, 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 people.

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.

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 EC Research does not imply that it will assume 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 ethics committee, even if the causal relationship with the study is unclear.

The EC approval given for a specific project, is valid for one year. We request you to inform us if the study will not be initiated or if the study does not start within 1 year after approval.

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

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

In case of a clinical trial (EudraCT), please be informed that the results must be published in the European Clinical Trial Register. The report of these results can be sent to the EC Research as the CSR.

Yours sincerely,

Prof. Dr. Minne Casteels
Chair
Ethics Committee Research UZ Leuven

Cc:
FAMHP (Federal Agency for Medicines and Health Products)

CTC (Clinical Trial Center UZ Leuven)