



afdeling Commissie Medische Ethiek
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Mw. mr. N.M.A. Verkleij

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onze referentie **P06.031/NV/nv**
uw referentie

datum 16 november 2016
onderwerp **Approval amendment**

aan De hooggeleerde vrouwe
prof. dr. C.L. Creutzberg

afdeling Radiotherapie
postzone **K1-P, alhier**

Geachte mevrouw,

Hereby I send you the decision of the Medical Ethics Committee (CME) of the LUMC on the research protocol titled: **"PORTEC-3: Randomized Phase III Trial Comparing Concurrent Chemoradiation and Adjuvant Chemotherapy with Pelvic Radiation Alone in High Risk and Advanced Stage Endometrial Carcinoma"** (P06.0674L).

The CME approves the amendment in the mentioned research project. For further considerations I refer you to the enclosed decision.

We kindly ask you to notify all parties involved in the research project of the decision.

Trusting to have provided you with sufficient information.

With kind regards,
on behalf of the Medical Ethics Committee

Mw. mr. N.M.A. Verkleij
Secretaris

cc: prof. dr. J.W.R. Nortier, Radiotherapie, LUMC, Leiden
C.M. van der Hulst, Klinische Farmacie en Toxicologie, LUMC, Leiden
CCMO d.m.v. upload in Toetsing OnLine (P06.0674L)



DECISION

Approval amendment

NL nummer	P06.0674L	CME nummer	P06.031
Titel onderzoek	"PORTEC-3: Randomized Phase III Trial Comparing Concurrent Chemoradiation and Adjuvant Chemotherapy with Pelvic Radiation Alone in High Risk and Advanced Stage Endometrial Carcinoma"		

Contact information: prof. dr. C.L. Creutzberg, Radiotherapie, LUMC, Leiden

Decision

The Medical Ethics Committee (CME) of the LUMC has considered, based on article 2, second paragraph, sub a of the law Medical Research Involving Human Subjects Act (WMO), the amendment belonging to the aforementioned research file.

The committee judges positively about the amendment

Documents

The decision is based on the documents mentioned in appendix 1.

Background

On 7 November 2016 the amendment was submitted at the CME for review. The amendment concerns the endorsement of the proposed 2017 time-based analysis, omission of the second interim analysis and the agreement to add a formal co-primary FFS endpoint with alpha adjustment.

Considerations

To the opinion of the CME all conditions mentioned in article 3 of the WMO are met.
To the opinion of the committee there are no direct consequences for local feasibility aspects.

Lastly, the CME points out that all obligations in the original decision have to be met.

Sincerely yours,
On behalf of the LUMC Medical Ethics Committee,

Mw. mr. N.M.A. Verkleij,
secretaris



Leiden, 16 november 2016

Appeal

Based on article 23 of the WMO someone with interest in the study can administratively appeal at the Central Commission for Human Research (CCMO) within six weeks of the date on which the decision is made. The appeal should be addressed to the CCMO, Postbus 16302, 2500 BH The Hague.

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Appendix 1

Documents research file

- A1. Cover letter as received d.d. 07-11-2016
- A1. Memo from TMG to DSMB regarding the timing of final analysis of the Portec-3 trial d.d. 05-09-2016
- C1. Research protocol 07-11-2016
- C2. Amendment d.d. 07-11-2016