**A radomized phase III trial comparing radical hysterectomy and pelvic node dissection vs simple hysterectomy and pelvic node dissection in patients with low-risk early-stage cervical cancer**

# The SHAPE-trial

# NCIG CTG Trial CX.5

**(protocol date 2012-JUL-06, Health Canada submission administrative update #2 2012-OCT-19)**

# Participation Dutch Gynaecological Oncology Group (DGOG)

**Principle DGOG investigator: CD de Kroon, Leiden University Medical Center**

# DGOG-specific appendix to the trial protocol (Protocol date 2012 July 06, Amendement #2 2014 AUG 27)

## STUDY ACKNOWLEDGEMENT / DISCLOSURE

Not applicable for the DGOG AND Not applicable for Dutch participating centers

## 2.7 HEALTH RELATED ECONOMIC EVALUATION

The Health-related economic evaluation is not applicable for the DGOG. Patients randomized by the DGOG are not able to participate in this part of the study because the instruments are not validated for the Dutch situation.

## 5.1 ELIGIBILITY CRITERIA

**5.1.8**
Patients fluent in English or Dutch must be willing to complete the quality of life questionnaires.

## 11.0 SERIOUS ADVERSE EVENTS

Apart from Serious Adverse Event reporting as mentioned in the protocol SEA's have to be reported according to the regulations of the Dutch Regulatory Body: the CCMO (Centrale Commissie Mensgebonden Onderzoek) and the Medical Ethical Board of the Leiden University Medical Center (METC LUMC). For the DGOG SAE will be reported according to the following protocol:

- the local investigator (or physician who detected the SAE) emails the digital DGOG SAE form to the IKNL-trial bureau as the SAE occurs but no later than 24 hours after the SAE has occurred.

- the IKNL-trial bureau forwards the SAE form to the responsible datamanager, the principal DGOG investigator and the NCIC

- the local investigator submits the complete preliminary Serious Adverse Event Report tot the NCIC CTG via the EDC system within 24 hours.

- the responsible datamanager updates the Serious Adverse Event Report as much as possible and submits the report to the NCIC CTG via the EDC within 10 days.

- the principal DGOG investigator is responsible for informing the CCMO and the METC LUMC.

## 13.1 CENTRAL REVIEW OF DIAGNOSTIC IMAGING AND QUALITY ASSURANCE PROCEDURE

It had been decided to not designate radiologists as local reference radiologists.

Dr T Bosse, gynaeco-pathologist at the Leiden University Medical Center, has been designated as Local Reference Pathologist with regard to inclusions in the LUMC

Dr PC Ewing, gynaeco-pathologist at the Erasmus Medical Center, has been designated as Local Reference Pathologist with regard to inclusions in the EMC

Dr K vd Vijver, gynaeco-pathologist at the Antoni van Leeuwenhoek Ziekenhuis, has been designated as Local Reference Pathologist with regard to inclusions in the AvL and the VUMc

Dr MCG Bleeker, gynaeco-pathologist at the Academic Medical Center, has been designated as Local Reference Pathologist with regard to inclusions in the Academic Medical Center

Prof Dr H Hollema, gynaeco-pathologist at the UMCG, has been designated as Local Reference Pathologist with regard to inclusions in the UMCG

Drs PJJM Klinkhamer, gynaeco-pathologist at the Catharina Ziekenhuis Eindhoven (COGZ), has been designated as Local Reference Pathologist with regard to inclusions in the Catharina Ziekenhuis

Dr P van Diest, gynaeco-pathologist at the UMCU, has been designated as Local Reference Pathologist with regard to inclusions in the UMCU'
Dr H Bulten, gynaeco-pathologist at the UMCN- St Radboud, has been designated as Local Reference Pathologist with regard to inclusions in the UMCN St Radboud'

## 15.0 PUBLICATION POLICY

Progress of the trial, interim analyses and newsletters as published by NCIC CTG will be published on the DGOG website in order to improve availability for Dutch participants. A digest of the primary trial outcomes will be made by the principal DGOG investigator as soon as they are available in order to inform participants. This digest will be made available on the DGOG website.

## 16.7 ON-SITE MONITORING / AUDITING

Site monitoring will be according to the 'DGOG Site Monitoring Protocol' which is developed at this moment. Until completion of the protocol with regard to the SHAPE trial all sites will be monitored at least once during inclusion and least 10% of cases will be reviewed during the site visit.

## APPENDIX 1 - PATIENT EVALUATION FLOW SHEET

Health Economics Questionnaire not applicable for patients randomized through the DGOG.

## APPENDIX VI – QUALITY OF LIFE ASSESSMENT

The questionnaires as included in the protocol (page 60-71) will be replaced by the translated and validated questionnaires in Dutch. The respective Dutch questionnaires are attached separately.

**LIST OF CONTACS**

Following contacts should be added:

Study supplies DGOG

http://www.DGOG.nl

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