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Authors: Packet Bram, Poppe Willy, Weynand Birgit, Vanherck Miet



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# The use of p16/Ki-67 dual staining technology on cervical cytology of patients undergoing a LLETZ procedure

Packet Bram, MD<sup>1</sup>; Poppe Willy, MD, PhD<sup>1</sup>; Weynand Birgit, MD, PhD<sup>2</sup>; Vanherck Miet<sup>2</sup>

1. Department of Gynaecology - University Hospitals of Leuven, Herestraat 49, Leuven, Belgium

2. Department of Pathology - University Hospitals of Leuven, Herestraat 49, Leuven, Belgium

Corresponding author:

Bram Packet

Noordstraat 50/9

1000 Brussel – Belgium

Tel: 0478/18.50.10

Email: bram.packet@gmail.com

## Abstract

**Objectives:** The main objective of this prospective observational study was to investigate the diagnostic performance of the p16/Ki-67 dual stain technique (DST) for detecting CIN 2+ in a LLETZ referral setting. Test performances were compared with HR-HPV testing and Pap cytology.

**Methods:** All patients referred for a LLETZ procedure were candidates for participation in this trial. A total of 110 patients were enrolled between October 2016 and March 2017. From each participant, a cervical cytology sample was obtained before the onset of the LLETZ procedure. On each sample, the dual stain technique (Roche CINtec PLUS ® test), Pap cytology and an HPV DNA assay (identifying 17 different HPV types) were performed.

**Results:** The overall disease prevalence of CIN 2+ was 56%. The mean age was 41 years, with 38% of patients being younger than 35 years.

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