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Management of ASC-US cytology has been widely studied in organized screening programs or controlled conditions. We compared under routine conditions of an opportunistic screening setting the effectiveness of immediate colposcopy (IC-arm), conventional cytology at 6/12 months (RC-arm) and triage with hrHPV test (HPV-arm) to identify CIN2/3+ during 2 years follow-up of 20-69 years old women with ASC-US in Medellin, Colombia. Between January, 2011 and January, 2014, 2,661 participants were equally randomized. All services but HC2-hrHPV test were routinely delivered by Healthcare Provider Institutions (HPIs). After 24 months since enrollment, women attended an exit visit and received cytology/hrHPV. ≥ASC-US/hrHPV+ were referred to colposcopy with a certified re-trained gynecologist. Routine diagnoses records and histological slides were ascertained from pathology laboratories. All CIN1+ and a subset of negatives and all diagnosis of exit visit were blindly confirmed by an expert panel of two well-trained pathologists. The primary (confirmed) and secondary (unconfirmed) endpoints were the CIN2/3+ cases detected during enrollment (first 6 months after recruitment), follow-up (>6 to <24 months or exit – whichever came first) and exit visit (>24 months). A total of 2,150 women that attended exit visit (n=2,117) or did not attend but had confirmed/unconfirmed routine CIN2/3+ (n=33) were included in the per-protocol analysis. Under routine conditions, HPV-arm detected 35% and 17% more unconfirmed CIN2/3+ cases than RC-arm and IC-arm during enrolment. There was a 2- (RC-arm and HPV-arm) and 3-fold (IC) increased in the number of CIN2/3+ cases after the confirmation of histopathological diagnoses. HPV and IC detected 20% and 13% more confirmed CIN2/3+ cases than RC during the enrollment and follow-up periods. Although under the routine conditions, HPV triage detected more CIN2/3+ cases, there is need to improve the histopathological

diagnosis to achieve a greater impact to prevent cancer in women with ASCUS cytology of Medellin, Colombia. ClinicalTrials.gov Identifier: NCT02067468

Key words: cervical cancer screening, triaging, pragmatic trial, health services research, implementation research.

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