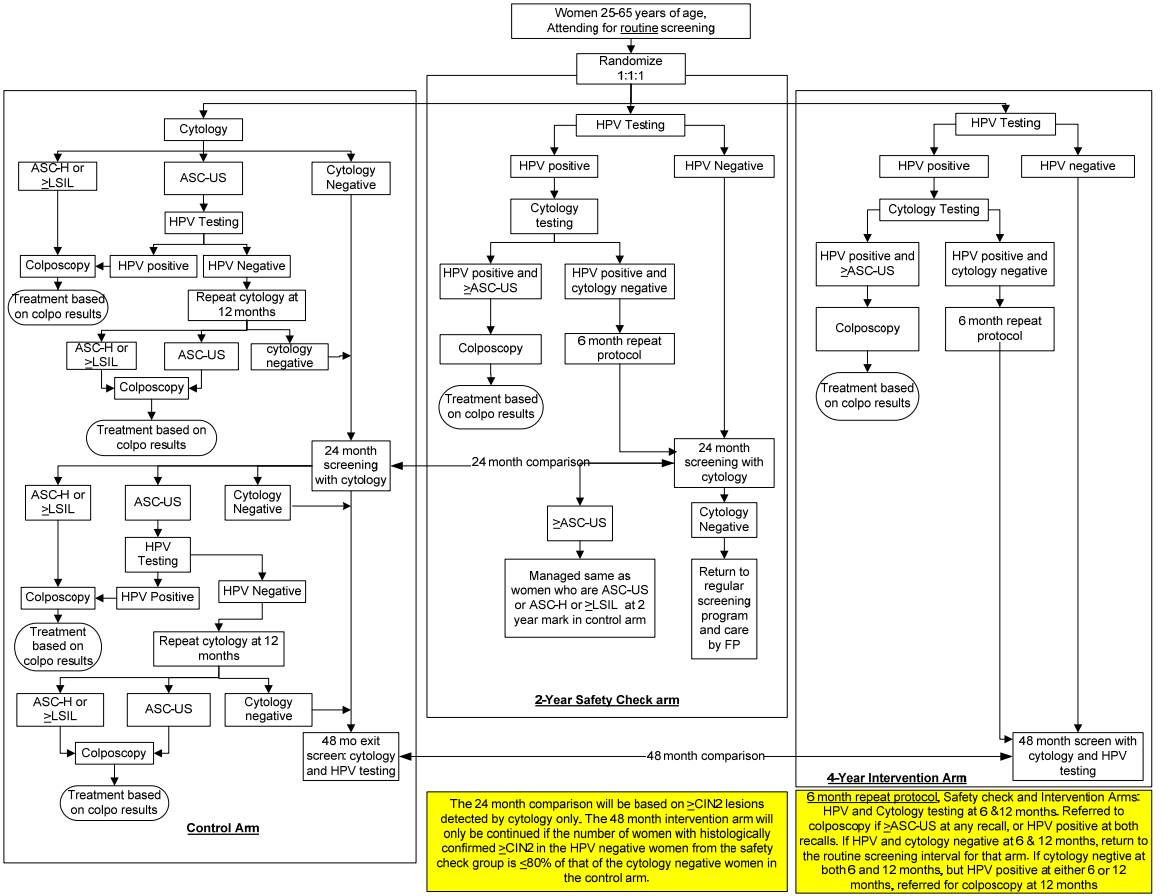
Women 25-65 years of age, Attending for routine screening
Randomize 1:1:1
Cytology
ASC-H or ≥LSIL
ASC-US
Cytology Negative
HPV Testing
Colposcopy
HPV positive
HPV Negative
Treatment based on colpo results
Repeat cytology at 12 months
ASC-H or ≥LSIL
ASC-US
cytology negative
Colposcopy
Treatment based on colpo results
24 month screening with cytology
ASC-H or ≥LSIL
ASC-US
Cytology Negative
HPV Testing
Colposcopy
HPV Positive
HPV Negative
Treatment based on colpo results
Repeat cytology at 12 months
ASC-H or ≥LSIL
ASC-US
Cytology negative
Colposcopy
Treatment based on colpo results
48 mo exit screen: cytology and HPV testing
Control Arm
HPV Testing
HPV positive
HPV Negative
Cytology testing
HPV positive and ≥ASC-US
HPV positive and cytology negative
Colposcopy
6 month repeat protocol
Treatment based on colpo results
24 month comparison
24 month screening with cytology
≥ASC-US
Cytology Negative
Managed same as women who are ASC-US or ASC-H or ≥LSIL at 2 year mark in control arm
Return to regular screening program and care by FP
2-Year Safety Check arm
HPV Testing
HPV positive
HPV negative
Cytology Testing
HPV positive and ≥ASC-US
HPV positive and cytology negative
Colposcopy
6 month repeat protocol
Treatment based on colpo results
48 month comparison
48 month screen with cytology and HPV testing
4-Year Intervention Arm
The 24 month comparison will be based on ≥CIN2 lesions detected by cytology only. The 48 month intervention arm will only be continued if the number of women with histologically confirmed ≥CIN2 in the HPV negative women from the safety check group is ≤80% of that of the cytology negative women in the control arm.
6 month repeat protocol, Safety check and Intervention Arms: HPV and Cytology testing at 6 &12 months. Referred to colposcopy if ≥ASC-US at any recall, or HPV positive at both recalls. If HPV and cytology negative at 6 & 12 months, return to the routine screening interval for that arm. If cytology negtive at both 6 and 12 months, but HPV positive at either 6 or 12 months, referred for colposcopy at 12 months