Review title
Date (dd/mm/yy )
Reviewer ID
Study ID

| | |
|---|---|
| Study title | |
| First author | |
| Source of publication<br>Journal yy;vol(iss):pp | |
| Language | |
| Publication type | journal □ abstract other (specify): …… |

Study eligibility/PICOS Scheme

| | |
|---|---|
| Population | women with primary vulval cancer in FIGO stage I or/and II, according FIGO classiffication<br>women with primary vulval cancer in T1-2,N0-1,M0 stage, according TNM classiffication<br>other |
| Intervention | Curative intent:<br>radical vulvectomy modyfied vulvectomy radiation chemotherapy |
| Comparison | no comparators<br>comparators used (specify)……<br>comparison within the same group of participants over time |
| Outcomes | morbidity mortality Quality of Life<br>none of the above |
| Study design | RCT non-randomised controlled study (specify): ……..<br>other (specify): …….. |

If included study is comparative experimental study, then go to the point A ,
If included study is comparative observational study, then go to the point B,
If included study is non- comparative study, then go to the point C

**PART A**
Comparative Experimental Studies:

1. Study characteristics

| Methods/methodological quality | |
|---|---|
| Study design | RCT NRS |
| RCT | |
| Method of randomization | specify and assess the method:<br>……<br>….<br>adequate inadequate unclear not reported |
| Allocation concealment | adequate inadequate unclear not reported<br>Describe…….. |
| Blinding | select blinded subjects:<br>patients investigators/clinicians outcomes assessors no blinding used<br>assess the method:<br>adequate inadequate unclear not reported |
| Information about drop outs | precise information (number of patients and reasons)<br>inaccurate information<br>lack of information |
| Rate of loss to follow-up | |
| Patients lost to follow-up analysed for adverse events | |
| Was the follow-up adequate to ascertain adverse effects? | Yes No Unclear<br>If "yes", specify…… |
| Statistical technique used | |
| Was adequate statistical analysis of potential confounders performed? | Yes No Unclear |
| Intention-to-treat analysis<br><br>What was the definition of ITT in the study? | implemented not implemented<br>……<br>……<br>…… |
| Sample size calculation | |
| Was the sensitivity analysis performed? | Yes No Not applicable |
| How problem with missing data was resolved? | |
| Were missing data accounted for in the analyses? | Yes No |
| Post hoc analysis | |
| Funding source | |

| NRS | |
|---|---|
| Control group selection | specify and assess the method:<br>……...<br>...<br>adequate inadequate unclear not reported |
| Allocation concealment | adequate inadequate unclear not reported<br>Describe…….. |
| Blinding | select blinded subjects:<br>patients investigators/clinicians outcomes assessors no blinding used<br>assess the method:<br>adequate inadequate unclear not reported |
| Information about drop outs | precise information (number of patients and reasons)<br>inaccurate information<br>lack of information |
| Rate of loss to follow-up | |
| Patients lost to follow-up analysed for adverse events | |
| Was the follow-up adequate to ascertain adverse effects? | Yes No Unclear<br>If "yes", specify…… |
| Statistical technique used | |
| Was adequate statistical analysis of potential confounders performed? | Yes No Unclear |
| Intention-to-treat analysis<br><br>What was the definition of ITT in the study? | implemented not implemented<br>……<br>……<br>…… |
| Sample size calculation | |
| Was the sensitivity analysis performed? | Yes No Not applicable |
| How problem with missing data was resolved? | |
| Were missing data accounted for in the analyses? | Yes No |
| Post hoc analysis | |
| Funding source | |

| Population | | |
|---|---|---|
| Trial inclusion criteria | | |
| Trial exclusion criteria | | |
| | Intervention group | Comparator/control group |
| Number of enrolled patients | | |
| Number of patients randomised, NR | | |
| Number of patients who completed treatment, n (%) | | |
| Number of patients available for follow up, n (%) | | |
| Age, in years<br>specify the measure:<br>..... | | |

| | | |
|---|---|---|
| Other baseline characteristics (FIGO or TNM stage, tumour size, deep of invasion, tumour cell type, site of disease) | | |
| Were treatment groups comparable at baseline? | Yes No<br>If “no” specify the reasons:<br>……<br>……<br>……<br>…… | |
| Treatment | | |
| Type of treatment used (technique, no. of sessions) | | |
| Treatment duration | | |
| Duration of follow up | | |
| Outcomes | | |
| Definition and unit of measurement | | |

Results
Dichotomous data

| Outcome:…… Follow up:…… | | | |
|---|---|---|---|
| Intervention group<br>NR / N = | | Control group<br>NR / N = | |
| N’ | n (%) | N’ | n (%) |
| | | | |
| Effect estimate RR OR ( 95% CI SE p) | | | |
| Blinding | select blinded subjects:<br>patients investigators/clinicians outcomes assessors no binding used<br>assess the method:<br>adequate inadequate unclear not reported | | |
| Incomplete outcome data addressed | | | |

N’ – number of evaluated patients; n – number of patients with outcome

Time-to-event data

| Outcome:…… Follow up:…… | | | |
|---|---|---|---|
| Intervention group<br>NR / N = | | Control group<br>NR / N = | |
| N’ | Median | N’ | Median |
| | | | |
| Effect estimate HR ( 95% CI SE p) | | | |
| Blinding | select blinded subjects:<br>patients investigators/clinicians outcomes assessors no binding used<br>assess the method:<br>adequate inadequate unclear not reported | | |
| Incomplete outcome data addressed | | | |

N’ – number of evaluated patients
Continuous data

| Outcome:…… Follow up:…… | | | | | | | |
|---|---|---|---|---|---|---|---|
| Intervention group<br>NR / N = | | | | Control group<br>NR / N = | | | |
| N’ | Mean value at baseline<br>( SD / SE / other) | Mean endpoint value<br>( SD / SE / other) | Mean change from baseline ( SD / SE / other) | N’ | Mean value at baseline<br>( SD / SE / other) | Mean endpoint value ( SD / SE / other) | Mean change from baseline ( SD / SE / other) |
| | | | | | | | |
| Blinding | select blinded subjects:<br>patients investigators/clinicians outcomes assessors no binding used<br>assess the method:<br>adequate inadequate unclear not reported | | | | | | |
| Incomplete outcome data addressed | | | | | | | |

N’ – number of evaluated patients

Reviewer's comments

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**PART B**

B) Comparative Observational Studies:

1. Study characteristics

| Methods/methodological quality | |
|---|---|
| Study design | Case – control Cohort |
| Case – Control | |
| Is case definition adequate? | independent validation record linkage self reported<br>none |
| Are the cases representative? | all cases arising from same population or group<br>not known |
| Selection of controls | same population as cases not known or no |
| Definition of controls | outcome of interest not present in history<br>no mention of history of outcome |
| Comparability of cases and controls | Yes No Unclear |
| Ascertainment of exposure to intervention | secure record<br>structured interview where blind to case/control status<br>interview not blinded to case/control status<br>written self report of medical record only<br>no description |
| Was the method of ascertainment of exposure for cases and controls the same? | Yes No Unclear |
| Non-response rate | same for both groups<br>non respondents described<br>rate different and no designation |
| Cohort | |
| Is the cohort representative | Yes No Unclear |
| Selection of non–exposed cohort | same population as exposed cohort not known or no |
| Ascertainment of exposure | secure record<br>structured interview<br>written self report<br>no description |
| Demonstration that outcome of interest wasn't present at start of study? | Yes No Unclear |
| Comparability of cohorts on the basis of the design or analysis | Yes No Unclear |
| Assessment of outcome | independent or blind assessment<br>record linkage self-report no description |
| Was follow-up long enough for outcomes to occur? | Yes No Unclear<br>If "yes", specify…… |
| Was follow-up of cohorts adequate? | complete follow-up<br>subjects lost to follow-up unlikely to introduce bias, small number lost (…..%)<br>follow-up rate ….%, and no description of this lost<br>no statement |
| | |
| Are the objectives or the hypothesis of the study stated? | Yes No Unclear |
| Method of allocation to groups | |
| For patients who weren't eligible for study, are the reasons why stated? | Yes No |
| Information about drop outs | precise information (number of patients and reasons) |

| | |
|---|---|
| | inaccurate information<br>lack of information |
| Statistical technique used | |
| Intention-to-treat analysis<br><br>What was the definition of ITT in the study? | implemented not implemented<br>……<br>……<br>…… |
| Sample size calculation | |
| Was loss to follow-up taken into account in the analysis? | Yes No |
| Were any confounders mentioned? | Yes, please describe…….. No |
| Were confounders accounted for in analyses? | Yes No |
| How problem with missing data was resolved? | |
| Were missing data accounted for in the analyses? | Yes No |
| Was the impact of biases assessed? | Yes No Not clearly assessed |
| Funding source | |

| Population | | |
|---|---|---|
| Trial inclusion criteria | | |
| Trial exclusion criteria | | |
| Is the target population defined? | Yes No | |
| | Intervention group | Comparator/control group |
| Number of included patients, N | | |
| Number of patients who completed treatment, n (%) | | |
| Age, in years<br>specify the measure:<br>..... | | |
| Other baseline characteristics (FIGO or TNM stage, tumour size, deep of invasion, tumour cell type, site of disease) | | |
| Were treatment groups comparable at baseline? | Yes No Not applicable<br>If "no" specify the reasons:<br>……<br>……<br>……<br>…… | |

| Treatment | |
|---|---|
| Type of treatment used (technique, no. of sessions) | |
| Treatment duration | |
| Duration of follow up | |

| Outcomes | |
|---|---|
| Definition and unit of measurement | |

Results

Dichotomous data

| Outcome:…… Follow up:…… | | | |
|---|---|---|---|
| Intervention group<br>NR / N = | | Control group<br>NR / N = | |
| N’ | n (%) | N’ | n (%) |
| | | | |
| Effect estimate RR OR ( 95% CI SE p) | | | |
| Blinding | select blinded subjects:<br>patients investigators/clinicians outcomes assessors no binding used<br>assess the method:<br>adequate inadequate unclear not reported | | |
| Incomplete outcome data addressed | | | |

N’ – number of evaluated patients; n – number of patients with outcome

Time-to-event data

| Outcome:…… Follow up:…… | | | |
|---|---|---|---|
| Intervention group<br>NR / N = | | Control group<br>NR / N = | |
| N’ | Median | N’ | Median |
| | | | |
| Effect estimate HR ( 95% CI SE p) | | | |
| Blinding | select blinded subjects:<br>patients investigators/clinicians outcomes assessors no binding used<br>assess the method:<br>adequate inadequate unclear not reported | | |
| Incomplete outcome data addressed | | | |

N’ – number of evaluated patients

Continuous data

| Outcome:…… Follow up:…… | | | | | | | |
|---|---|---|---|---|---|---|---|
| Intervention group<br>NR / N = | | | | Control group<br>NR / N = | | | |
| N’ | Mean value at baseline<br>( SD / SE / other) | Mean endpoint value<br>( SD / SE / other) | Mean change from baseline ( SD / SE / other) | N’ | Mean value at baseline<br>( SD / SE / other) | Mean endpoint value ( SD / SE / other) | Mean change from baseline ( SD / SE / other) |
| | | | | | | | |
| Blinding | select blinded subjects:<br>patients investigators/clinicians outcomes assessors no binding used<br>assess the method:<br>adequate inadequate unclear not reported | | | | | | |
| Incomplete outcome data addressed | | | | | | | |

N’ – number of evaluated patients

Reviewer's comments

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**PART C**

Non-Comparative Studies:

Quality assessment according checklist from “Methods for the development of NICE public health guidance (second edition)”

Type of study……...

Methodology description……

| Population | |
|---|---|
| Trial inclusion criteria | |
| Trial exclusion criteria | |
| Number of enrolled patients | |
| Number of patients who completed treatment, n (%) | |
| Number of patients available for follow up, n (%) | |
| Age, in years<br>specify the measure:<br>..... | |
| Other baseline characteristics (FIGO or TNM stage, tumour size, deep of invasion, tumour cell type, site of disease) | |
| Treatment | |
| Type of treatment used (technique, no. of sessions) | |
| Treatment duration | |
| Duration of follow up | |
| Outcomes | |
| Definition and unit of measurement | |
| | |

Results

Dichotomous data

| Outcome:…… Follow up:…… | |
|---|---|
| Intervention group | |
| N | n (%) |
| | |
| ( 95% CI SE p) | |
| Incomplete outcome data addressed | |

N' – number of evaluated patients; n – number of patients with outcome

Time to event data

| Outcome:…… Follow up:…… | |
|---|---|
| Intervention group | |
| N | Median |
| | |
| ( 95% CI SE p) | |
| Incomplete outcome data addressed | |

N' – number of evaluated patients; n – number of patients with outcome

Continuous data

| Outcome:…… Follow up:…… | | | |
|---|---|---|---|
| Intervention group | | | |
| N | Mean value at baseline ( SD / SE / other) | Mean endpoint value ( SD / SE / other) | Mean change from baseline ( SD / SE / other) |
| | | | |
| p | | | |
| Incomplete outcome data addressed | | | |

N' – number of evaluated patients; n – number of patients with outcome