

Checklist Randomised Controlled Trials Lezoché 2012 ¹

Internal validity

- The study addresses an appropriate and clearly focused question
Yes
- The assignment of subjects to treatment groups is randomized
Yes – computer-generated randomisation
- An adequate concealment method is used
Yes – opaque sealed envelopes
- Subjects are kept blind about treatment allocation
No
- Outcome assessors are kept blind about treatment allocation
Not reported but unlikely
- The treatment and control groups are similar at the start of the trial
Yes
- The only difference between groups is the treatment under investigation
Yes
- All relevant outcomes are measured in a standard, valid and reliable way
Yes
- All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)
Yes

Overall assessment of the study

- Are the results of the study:
 - valid? Yes
 - applicable to the patient group targeted in the search question? Yes

Checklist COHORT studies Callender 2010 ²

Internal validity

- The study addresses an appropriate and clearly focused question
Yes
- The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
- The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
- Comparison by exposure status is made between full participants and those lost to follow up
Not applicable
- The outcomes are clearly defined
Yes
- The assessment of outcome is made blind to exposure status
Not reported but unlikely
- The measure of assessment of exposure is reliable
Not applicable
- The main potential confounders are identified and taken into account in the design and analysis
Identified: yes, not taken into account in the analysis

Overall assessment of the study

- Are the results of the study:
 - valid? yes
 - applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Guerrieri 2008 ³

Internal validity

The study addresses an appropriate and clearly focused question

Yes

The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation

Yes

The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis

Not applicable

Comparison by exposure status is made between full participants and those lost to follow up

Not applicable

The outcomes are clearly defined

Yes

The assessment of outcome is made blind to exposure status

Not applicable

The measure of assessment of exposure is reliable

Not applicable

The main potential confounders are identified and taken into account in the design and analysis

No

Overall assessment of the study

Are the results of the study:

- valid? yes
- applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Kennelly 2012 ⁴

Internal validity

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Yes

The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation

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Not applicable

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Not applicable

The outcomes are clearly defined

Yes

The assessment of outcome is made blind to exposure status

Not applicable

The measure of assessment of exposure is reliable

Not applicable

The main potential confounders are identified and taken into account in the design and analysis

No

Overall assessment of the study

Are the results of the study:

- valid? yes
- applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Luglio 2011 ⁵

Internal validity

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The outcomes are clearly defined

Yes

The assessment of outcome is made blind to exposure status

Not applicable

The measure of assessment of exposure is reliable

Not applicable

The main potential confounders are identified and taken into account in the design and analysis

No

Overall assessment of the study

Are the results of the study:

- valid? yes; though unclear whether all T1 patients did get neoadjuvant radiotherapy
- applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Meadows 2006 ⁶

Internal validity

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The outcomes are clearly defined

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The assessment of outcome is made blind to exposure status

Not applicable

The measure of assessment of exposure is reliable

Not applicable

The main potential confounders are identified and taken into account in the design and analysis

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Overall assessment of the study

Are the results of the study:

- valid? yes
- applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Mohiuddin 1994 ⁷

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The measure of assessment of exposure is reliable

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The main potential confounders are identified and taken into account in the design and analysis
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Overall assessment of the study

Are the results of the study:

- valid? yes
- applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Nair 2008⁸

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Overall assessment of the study

Are the results of the study:

- valid? yes
- applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Schell 2002⁹

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The main potential confounders are identified and taken into account in the design and analysis

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Overall assessment of the study

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- valid? yes
- applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Tennyson 2012 ¹⁰

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- applicable to the patient group targeted in the search question? yes

Checklist COHORT studies Yeo 2010 ¹¹

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1. Lezoche E, Baldarelli M, Lezoche G, Paganini AM, Gesuita R, Guerrieri M. Randomized clinical trial of endoluminal locoregional resection versus laparoscopic

- total mesorectal excision for T2 rectal cancer after neoadjuvant therapy. *British Journal of Surgery*. 2012;99(9):1211-8.
2. Callender GG, Das P, Rodriguez-Bigas MA, Skibber JM, Crane CH, Krishnan S, et al. Local excision after preoperative chemoradiation results in an equivalent outcome to total mesorectal excision in selected patients with T3 rectal cancer. *Ann Surg Oncol*. 2010;17(2):441-7.
 3. Guerrieri M, Baldarelli M, Organetti L, Grillo Ruggeri F, Mantello G, Bartolacci S, et al. Transanal endoscopic microsurgery for the treatment of selected patients with distal rectal cancer: 15 years experience. *Surg Endosc*. 2008;22(9):2030-5.
 4. Kennelly RP, Heeney A, White A, Fennelly D, Sheahan K, Hyland JM, et al. A prospective analysis of patient outcome following treatment of T3 rectal cancer with neo-adjuvant chemoradiotherapy and transanal excision. *Int J Colorectal Dis*. 2012;27(6):759-64.
 5. Luglio G, Celentano V, Tarquini R, Sollazzo V, Giglio MC, Bucci L. Functional and oncological outcomes after transanal local excision for rectal cancer. A prospective study. *European Journal of Surgical Oncology*. 2011;37 (12):S4.
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 7. Mohiuddin M, Marks G, Bannon J. High-dose preoperative radiation and full thickness local excision: a new option for selected T3 distal rectal cancers. *International journal of radiation oncology, biology, physics*. 1994;30(4):845-9.
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 10. Tennyson N, Mendenhall WM, Morris CG, Huang EH, Zlotecki RA. Transanal excision with radiation therapy for rectal adenocarcinoma. *Clin Med Res*. 2012;10(4):224-9.
 11. Yeo SG, Kim DY, Kim TH, Kim SY, Chang HJ, Park JW, et al. Local excision following pre-operative chemoradiotherapy-induced downstaging for selected cT3 distal rectal cancer. *Jpn J Clin Oncol*. 2010;40(8):754-60.