

Table 2. Characteristics of included studies – Behandeling ongecompliceerde galstenen

Study	Participants	Comparison	Follow-up	Outcome measures	Comments	Risk of bias (per outcome measure)*
<i>Individual studies</i>						
Comes, 2024 SECURE trial	N at baseline Intervention: 661 Control: 665 Age (median, IQR) Intervention: 48.0 (37.0-59.0) Control: 49.0 (39.0-58.0) Sex (male/female) Intervention: 131/399 Control: 150/387 Abdominal pain (VAS pain)	Intervention: Restrictive strategy group (advice to perform a laparoscopic cholecystectomy was displayed by the triage instrument for patients who fulfilled all 5 prespecified criteria of the triage instrument, patients who did not meet the criteria were selected for conservative treatment.) Control: usual care (patients received the standard care given in the participating centers, and selection for cholecystectomy was left to the discretion of the surgeon in shared decision with the patient.)	1 year and 5 years	Pain (patient-reported) Pain-free Cholecystectomy Surgical complications Gallstone complications	Source of funding: the initial SECURE study was funded by the Netherlands Organization for Health Research and Development and CZ Healthcare Insurance. This follow-up study was not funded. Conflicts of interest: None reported.	Some concerns (patient- reported outcomes)

	score, median, IQR) Intervention: 7.5 (5.5-8.8) Control: 7.5 (5.4-8.7)					
Innes, 2024	N at baseline Intervention: 217 Control: 217 Age (mean, SD) Intervention: 50.4 ± 15.1 Control: 50.5 ± 15.3 Sex (male/female) Intervention: 46/171 Control: 47/170	Intervention: Observation/conservative management Control: laparoscopic cholecystectomy	24 months	Pain (SF-36 norm-based bodily pain score) at 24 months Patient-reported health-related quality of life (SF-36 norm-based bodily pain) at 24 months Complications at 18 months Complications at 24 months Total NHS costs (mean ± SD): QALYs (mean ± SD)	Source of funding: Funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme. Conflicts of interest: Different grants and other financial interests were reported by the authors.	LOW (all outcomes)
Latenstein, 2022 SECURE trial	N at baseline Intervention: 530 Control: 537	Intervention: Restrictive strategy group (advice to perform a laparoscopic cholecystectomy was	12 months	Cost-effectiveness Use of resources	Source of funding: the initial SECURE study was funded by the Netherlands Organization for Health Research and	LOW (all outcomes)

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	<p>Age (mean, SD)</p> <p>Intervention: 48.0 years (37.0-59.0)</p> <p>Control: 49.0 years (39.0-58.0)</p> <p>Sex (male/female)</p> <p>Intervention: 131/399</p> <p>Control: 150/387</p> <p>Abdominal pain (VAS pain score, median, IQR)</p> <p>Intervention: 7.5 (5.5-8.8)</p> <p>Control: 7.5 (5.4-8.7)</p>	<p>displayed by the triage instrument for patients who fulfilled all 5 prespecified criteria of the triage instrument, patients who did not meet the criteria were selected for conservative treatment.)</p> <p>Control: usual care (patients received the standard care given in the participating centers, and selection for cholecystectomy was left to the discretion of the surgeon in shared decision with the patient.)</p>		<p>Cholecystectomy (mean volume, BCa 95% CI)</p> <p>Overall saving in healthcare:</p> <p>ICER (incremental cost-effectiveness ratio) per patient being free of pain at twelve months</p>	<p>Development and CZ Healthcare Insurance. This follow-up study was not funded.</p> <p>Conflicts of interest: not reported.</p>	
<p>Van Dijk, 2019</p> <p>SECURE trial</p>	<p>N at baseline</p> <p>Intervention: 661</p> <p>Control: 665</p>	<p>Intervention: Restrictive strategy group (advice to perform a laparoscopic cholecystectomy was</p>	<p>12 months</p>	<p>Time to being pain free in months (irrespective of surgical or conservative treatment)</p>	<p>Source of funding: The SECURE study was funded by the Netherlands Organization for Health Research and</p>	<p>Some concerns (patient-reported outcomes)</p>

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<p>Schmidt, 2011</p> <p>(Long-term follow-up van Vetrhus)</p>	<p>N at baseline</p> <p>Intervention: 69</p> <p>Control: 68</p> <p>Age (mean)</p> <p>Total: 49.7 years (range 20-79)</p>	<p>Intervention: Observation</p> <p>Control: Surgery</p>	<p>14 years</p>	<p>Events after randomization + postoperative events</p> <p>Actual final treatment (cholecystectomy)</p>	<p>Source of funding: The concluding phase of the study was given financial support by the Haraldsplass Deaconal Hospital and the Western Norway Regional Health Authority through the Centre for Clinical Research at Haukeland University Hospital.</p> <p>No conflicts of interest.</p>	<p>LOW (all outcomes)</p>

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	Sex (male/female) Total: 25/112					
Vetthus, 2004	N at baseline Intervention: 69 Control: 68 Age (mean, SD) Intervention: -women: 48 (22-75) -men: 60 (39- 79) Control: -women: 52 (20-77) -men: 52 (27- 74) Sex (male/female) Intervention: 12/57 Control: 13/55	Intervention: Observation Control: Surgery	5 years	Cholecystectomy Gallstone-related events Health-related quality of life Pain score	Source of funding: The concluding phase of the study was given financial support by the Haraldsplass Deaconal Hospital and the Western Norway Regional Health Authority through the Centre for Clinical Research at Haukeland University Hospital. Conflicts of interest: not reported.	Some concerns (patient- reported outcomes)

**For further details, see risk of bias table in the appendix*