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1 **Title:** The CABI trial: An unblinded parallel group randomised controlled feasibility trial of long
2 course antibiotic therapy (28 days) compared to short course (≤ 10 days) in the prevention of
3 relapse in adults treated for Complicated intra-ABdominal Infection.

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14 0134), Dermot Burke (0000-0002-4342-7464) and Andrew Kirby (0000-0002-2440-9316).

15 **Author Contributions:** All authors contributed to the study conception, design, material
16 preparation, data collection and analysis. The first draft of the manuscript was written by
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23

24 **Abstract**

25 **Purpose:** Relapse after complicated intra-abdominal infection (cIAI) remains common after
26 treatment. The optimal antibiotic treatment duration for cIAIs is uncertain, especially in cases
27 where source control is not achieved. We hypothesised that in patients with cIAIs, regardless
28 of source control intervention, there would be a lower relapse rate with long course antibiotics
29 (28 days) compared to short course (≤ 10 days). We piloted a trial comparing ≤ 10 days to 28
30 days antibiotics for cIAI.

31 **Methods:** A randomised controlled unblinded feasibility trial was conducted. Eligible
32 participants were adult patients with a cIAI that was diagnosed ≤ 6 days prior to screening.
33 Randomisation was to long course (28 days) or short course (≤ 10 days) antibiotic therapy.
34 Choice of antibiotics was determined by the clinical team. Participants were followed up for 90
35 days. Primary outcomes were willingness of participants to be randomised and feasibility of
36 trial procedures.

37 **Results:** In total, 172 patients were screened, 84/172 (48.8%) were eligible and 31/84 (36.9%)
38 were randomised. Patients were assigned to either the short course arm (18/31, 58.0%) or the
39 long course arm (13/31, 41.9%). One patient in the short course arm withdrew after
40 randomization. In the short course arm, 4/17 (23.5%) were treated for a cIAI relapse vs 0/13
41 (0.0%) relapses in the long course arm. Protocol violations included deviations from protocol
42 assigned antibiotic duration and interruptions to antibiotic therapy.

43 **Conclusions:** This feasibility study identified opportunities to increase recruitment in a full
44 trial. This study demonstrates completion of a randomized controlled trial to further evaluate
45 the optimum antibiotic duration for cIAIs is feasible.

46 **Trial registration:** NCT03265834.

47 **Key words:** Antibiotic; Complicated intra-abdominal infection; duration; trial

48

49 **Introduction**

50 Complicated intra-abdominal infections (cIAs) extend beyond the hollow viscus of origin into
51 the peritoneal space and are associated with either abscess formation or peritonitis [1]. They
52 are heterogeneous in aetiology and include spontaneous infections arising from a perforated
53 intra-abdominal viscus, and post-operative infections. Despite the varied origin of these
54 infections, there are similar management strategies that centre on source control, e.g.
55 drainage of intra-abdominal fluid collections, and administration of antibiotic therapy. These
56 infections are challenging to manage, in part due to the varied pathology that causes them,
57 and are associated with significant morbidity and mortality [2, 3]. Despite this burden of
58 disease, there is little clinical evidence on which to base antibiotic treatment. At present there
59 have been two trials into antibiotic durations for cIAI. The STOP-IT trial [4], which compared 4
60 vs. 8 days (median durations) found that longer durations significantly reduced the time until
61 relapse ($p < 0.001$). The DURAPOP trial compared 8 to 15 days duration and found a lower
62 rate of clinical failure in patients with the longer course antibiotics, 24% (28/120) with 8 days
63 and 14% (16/116) with 15 days ($p = 0.54$) [5]. Given that there remains a high relapse rate, it
64 has been suggested that longer courses of antibiotics may reduce relapse of cIAs [6]. In the
65 UK, for serious infections (brain abscess, mastoiditis, septic arthritis, osteomyelitis, lung
66 abscess, endocarditis, and prostatitis) which have a high risk of relapse and associated
67 mortality, microbiologists often recommend up to and beyond four weeks of antibiotic therapy.
68 This approach has not yet been investigated in a RCT for cIAs. **Furthermore, around 30%**
69 **of patients in England and Scotland, do not undergo source control procedures [7] and**
70 **thus far there have been no trials evaluating antibiotic duration in this patient group.**
71 We therefore hypothesise that in patients with cIAs, regardless of source control intervention;
72 there will be a lower relapse rate when treated with 28 days of antibiotics compared to ≤ 10
73 days of antibiotics.

74 **Materials and Methods**

75 **Trial design:** An unblinded parallel group randomised controlled feasibility trial comparing
76 long course (28 days) to short course (≤ 10 days) antibiotic therapy in patients with cIAI was
77 carried out. This feasibility trial was approved by the Yorkshire and Humber (Leeds–East)

78 Research Ethics Committee, UK (16/YH0453) (ClinicalTrials.gov Identifier: NCT03265834).
79 The study is reported according to the CONSORT extension to pilot and feasibility trials, see
80 supplementary material.

81 **Participants:** Participants were eligible if they were aged ≥ 18 years old and had been
82 diagnosed with a cIAI. The diagnostic criteria for a cIAI diagnosis included the presence of
83 both radiological and clinical features consistent with a cIAI, including a fever (temperature of
84 ≥ 38 °C) and a neutrophilia ($> 7.5 \times 10^9/L$) or intra-operative confirmation of an abscess. Any
85 cIAI diagnosed >6 days prior to screening was excluded. Patients were identified either by
86 notification by a member of the patient's clinical team to the research team, or by screening of
87 radiology reports. Participants were excluded if their cIAI was associated with uncomplicated
88 appendicitis, primary complicated appendicitis, pancreatitis, pelvic inflammatory disease,
89 primary (spontaneous) bacterial peritonitis (SBP), continuous ambulatory peritoneal dialysis
90 peritonitis (CAPD peritonitis) and *Clostridium difficile* infection as they were consider distinct
91 conditions with separate management strategies. Patients were recruited from Leeds
92 Teaching Hospitals NHS trust in the United Kingdom between August 2017 and June 2018.
93 The trial was stopped at the end of funding for the trial research staff.

94 **Interventions:** Participants received either ≤ 10 days (short course [SC]) or 28 days (long
95 course [LC]) of antibiotic therapy. The clinical team caring for the patient determined the choice
96 of antibiotic, as the aim was to compare antibiotic prescribing strategies (i.e. short course vs
97 long course) rather than individual drugs or specified combinations of drugs. **The antibiotic
98 prescribed was chosen according to the available clinical and microbiological data, in
99 conjunction with local antibiotic guidelines, and altered as new results and clinical
100 information become available.**

101 **Outcomes:** The primary outcomes were to determine trial feasibility and included: the
102 willingness of participants to be randomised, the willingness of clinicians to allow patients to
103 be recruited, the number of eligible patients and follow up rates. Additionally, data on clinical
104 objectives that would be the primary and secondary objectives for a definitive study following
105 on from the feasibility study were collected in order to determine the feasibility of collecting
106 this information. These clinical objectives included rate of relapse, mortality, total days of

107 antibiotic consumption, all infections within 90 days of cIAI diagnosis, length of hospital stay
108 and number of source control procedures required. Participants were followed up for 90 days
109 and outcomes assessed at 30 days and 90 days post cIAI diagnosis (via telephone
110 consultation or inpatient review).

111 **Relapse of cIAI was defined as relapse of infection occurring after surgical and antibiotic**
112 **therapy to manage the primary CABI had been considered successful (as demonstrated**
113 **by antibiotics being stopped and no further source control procedures planned).**
114 **Relapse of cIAI included both definite and probable cases. A definite case was defined**
115 **as cIAI relapse with a combination of radiological and clinical features consistent with**
116 **CABI including a fluid collection, a temperature of ≥ 38 degrees and a neutrophilia**
117 **(neutrophil count $> 7.5 \times 10^9/L$) or intra-operative confirmation of an abscess. Probable**
118 **cIAI relapse included cases where there was either absence of radiological imaging or**
119 **radiological features inconsistent with a cIAI, but where no other source of infection**
120 **was identified, and the patient was managed for a relapsed cIAI.**

121 Quality of life was assessed with the European Quality of Life–5 Dimensions 3-Level
122 questionnaire (EQ-5D-3L) and the EQ-5D visual-analogue scale (EQ-5D VAS) at baseline,
123 day 30, day 90 and at the time of cIAI relapse.

124 **Sample size:** Given that this was a feasibility study, no formal sample size calculation was
125 performed and a maximum patient recruitment target of 60 patients was set [8].

126 **Randomisation:** Patients in each intervention arm were stratified into two groups; post-
127 operative cIAIs (cIAI within 90 days of surgery) and non post-operative cIAIs (primary cIAIs).
128 Simple randomisation with a 1:1 allocation ratio was then used to allocate patients.

129 **Sequence generation:** A web based sequence generator was used to generate an
130 unpredictable allocation sequence (<https://www.random.org/sequences/>).

131 **Allocation concealment:** An independent person outside of the research team transferred
132 the sequence into sealed envelopes, which were then accessed after trial enrolment to
133 allocate participants to a treatment arm.

134 **Implementation:** Patient's allocation was determined by a trial researcher (SA, RA & RB)
135 after a patient had given their consent.

136 **Blinding:** Patients, researchers and clinicians were not blinded to the treatment allocation.

137 **Statistical methods:** Descriptive statistics **were** used to report outcomes and baseline
138 characteristics. Continuous data are summarised as medians and interquartile ranges (IQR)
139 and categorical data were summarised as proportions (percentage). For clinical outcome
140 analysis, intention to treat analysis was completed. Sub-group analysis of post-operative cIAls
141 vs non post-operative cIAls was also completed. All analyses were conducted using the
142 statistical package SPSS (IBM SPSS Statistics for Windows, Version 23.0, IBM Corp).

143 **Protocol amendments:** One protocol amendment was made and implemented during the
144 study and the substantial changes included the following: The exclusion of any patients who
145 had a cIAI in the previous one year was changed to three months to allow inclusion of more
146 patients with cIAls. The definition of cIAI was amended to include patients with fever prior to
147 admission and patients who have evidence of purulent peritonitis intra-operatively. An
148 amendment that was approved but not implemented was for the recruitment of patients via
149 consultee consent.

150 **Results**

151 **Participant flow:** From August 2017 to June 2018, 172 patients were assessed for eligibility,
152 84/172 (48.8%) were eligible for enrolment and 31/84 (36.9%) were enrolled and randomised.
153 Eight-eight patients were ineligible, of whom 42 (47.7%) were being treated for a cIAI but did
154 not have a fever and a raised neutrophil count and 14 (15.9%) patients were ineligible because
155 they had had >6 days of antibiotics for their cIAI. Of the 53/84 (63.1%) patients who were
156 eligible but not enrolled; 32 declined participation (Table 1), 13 were either discharged or had
157 antibiotics discontinued before consent or approach by the research team, two were not
158 enrolled at the request of the treating surgeon, two died prior to approach and four were not
159 recruited for other reasons (one patient was non-english speaking, one was breastfeeding,
160 one was due to undergo major surgery for another indication and one was unable to be
161 followed up due to travel outside of the continent). Patients who declined to participate in the
162 study were more likely to have had a HDU/ICU admission (13.3% of patients who consented

163 to participate had a HDU/ICU admission vs 25.0% of patients who declined to participate).
164 Reasons for declining to participate included a preference for an antibiotic duration (4/32),
165 feeling too unwell (4/32), concern over adverse events (3/32), but most commonly no reason
166 was given (20/32). One patient withdrew from the study after randomisation, the remaining
167 30/31 randomised patients were followed up for the complete study period. Participant flow is
168 outlined in the Consolidated Standards of Reporting Trials (CONSORT) flow diagram in Figure
169 1.

170 **Protocol adherence:** Participants were deemed to have received allocated treatment if in the
171 SC arm they received < 10 days (+1) and in the LC arm 28 days (+/- 1). In the SC treatment
172 arm, 4/17 (24%) patients continued antibiotics for longer than the allocated duration; two
173 received 14 days and two received 12 days treatment. Whereas, 5/13 (38%) patients in the
174 LC treatment arm did not receive the allocated treatment duration of antibiotics; one patient
175 discontinued early at day 20 due to a serious adverse event (SAE) from co-amoxiclav
176 (deranged liver function tests), three patients had their antibiotics stopped early (days 4, 5 and
177 15) inadvertently by members of the clinical team who were unaware of treatment allocation
178 and one patient continued antibiotics for 30 days.

179 **Baseline data:** The baseline characteristics of patients enrolled in the study are summarised
180 in Table 2. Characteristics of patients in each arm of the study were comparable apart from
181 the number of patients with post-operative cIAIs, which was higher in the short course arm
182 (59% vs 31%).

183 **Numbers analysed, Outcomes and Estimations**

184 **Intention to treat (ITT) analysis:** Overall 4/30 (13.3%) patients had either a definite or
185 probable cIAI relapse, all of whom were randomised to receive short course antibiotics.

186 Only one patient died during the study, this patient was randomised to receive 28 days of
187 antibiotics however treatment was stopped early on day four of treatment. The overall hospital
188 stay was 8 days (IQR 4.5-11) in patients who had long course antibiotics and 9 days (IQR 4.5-
189 31) in patients who had short course antibiotics. A higher proportion of patients in the SC arm
190 had other infection diagnoses during the follow up period compared to the LC arm (6/17

191 [35.3%] vs 1/13 [7.9%]). Clinical outcomes are shown in Table 3, and characteristics by
192 presence or absence of relapse are shown in Table 4.

193 **Sub group analysis:** In total, 14/30 (46.7%) patients had a post-operative cIAI (cIAI within 90
194 days of abdominal surgery). Of these, four received long course antibiotics and ten short
195 course antibiotics. Out of the four patients who had a cIAI relapse, three had post-operative
196 cIAIs.

197 **Quality of life analysis:** In total, 26/30 participants completed EQ-5D-3L and EQ-VAS
198 questionnaires for all time points. For the baseline assessments, data on 1/30 EQ-5D-3L and
199 2/30 EQ-VAS were missing. One patient died before day 30 assessments took place, and 1/29
200 day 30 EQ-VAS and 1/29 day 90 EQ-VAS were missing. All four patients who had a cIAI
201 relapse completed a EQ-5D-3L and EQ-VAS questionnaires at the time of cIAI relapse.

202 **Source control procedures: Overall, eight patients did not undergo source control**
203 **procedures. Six patients in the SC arm did not undergo source control: three of these**
204 **patients had post-operative cIAIs, two had complicated diverticular disease and one**
205 **had perforated peptic ulcer. Two patients in the LC arm did not undergo source control;**
206 **both had cIAI due to complicated diverticulitis.**

207 **Of the 11/13 patients who had source control in the LC arm, three had percutaneous**
208 **drainage and eight had surgical procedures (four had resection with anastomosis or**
209 **closures and four had resection with proximal diversion. In the SC arm, 7/17 had**
210 **percutaneous drainage and 4/17 had surgical source control (one had surgical drainage,**
211 **one had closure of perforation with a washout and two had surgical resection with**
212 **proximal diversion).**

213 **Antibiotic treatment:** The median antibiotic treatment duration was 9 days (IQR 7.5 - 11.5)
214 in the group of patients receiving SC antibiotics and 28 days (IQR 17.5 - 28.0) in the group
215 receiving LC antibiotics. The most frequently used intravenous antibiotic regimen was
216 cefuroxime and metronidazole, which was used in 14/30 (46.7%) participants (6 patients in
217 LC arm and 8 patients in SC). Piperacillin-tazobactam was the second commonest antibiotic
218 regimen and used in 7/30 (23.3%) patients (6 patients in the SC and 1 in the LC arm).
219 Amoxicillin plus clavulanic acid was the most frequently used oral regimen; 13/30 (43.3%)

220 patients (6 in the SC arm and 7 in the LC arm). Two patients out of the 13 patients in the SC
221 arm had interruptions to their antibiotic course (antibiotics stopped and restarted), this led to
222 one patient receiving antibiotics for longer than the assigned duration. Overall, seven patients
223 had their initial antibiotic regimen altered due to the presence of resistant organisms; 3/11
224 (27.2%) in the LC arm and 4/16 (25.0%) in the SC arm.

225 **Harms:** One SAE related to the study occurred in a patient allocated to receive LC who
226 developed deranged liver function tests (LFTs) which normalised after cessation of antibiotics.
227 Other SAEs that occurred which were unrelated to the study procedures included: small bowel
228 obstruction secondary to adhesions, stroke, acute kidney injury, episode of uncomplicated
229 diverticulitis and pulmonary embolus. **There were no episodes of *Clostridium difficile***
230 **infection.**

231 **Discussion**

232 The optimal antibiotic treatment strategy for cIAIs remains uncertain especially in cases where
233 it is not feasible to perform source control. To date there have been two RCTs which have
234 evaluated antibiotic duration for cIAIs where source control has been achieved. The STOP IT
235 trial reported that in patients who had adequate source control, short course antibiotic therapy
236 (median 4 days) was as effective as long course therapy (median 8 days) [4]. The DURAPOP
237 trial assessed antibiotic duration for intensive care patients and compared eight days to fifteen
238 days of antibiotic therapy [5]. The primary outcome was antibiotic free days within the 45 days
239 after source control and results favoured 8 days of treatment (median number of antibiotic-
240 free days 15 [6-20] vs 12 [6-13] days). However in both trials clinical failure was common (15-
241 24%). One reason for relapse of cIAI may be that antibiotic treatment may not have been given
242 for long enough to eradicate bacteria from, what should be, a sterile intra-abdominal cavity.
243 Thus, long course antibiotic therapy may reduce the rate of cIAI relapse .

244 This RCT of short course (≤ 10 days) or long course (28 days) antibiotic therapy for cIAIs was
245 designed to determine the feasibility of conducting a definitive RCT. An adequate proportion
246 (36.7%) of eligible patients were enrolled which suggests that it would be feasible to enrol
247 patients into such a definitive trial. Additionally, with the exception of two cases, clinicians were
248 willing for patients to be recruited and patients were able to successfully complete follow-up.

249 Whilst our recruitment target of 60 patients was not reached, we recruited sufficient patients
250 to be able to determine trial feasibility.

251 During the trial there were minimal data missing on primary and secondary outcome
252 measures, with the exception of EQ-5D questionnaires. However, the rate of missing data was
253 low, therefore using EQ-5D questionnaires to calculate QALYs for economic evaluation will
254 still be a feasible in a definitive trial. **Overall, protocol adherence was 70%, in keeping with**
255 **other trials that dictate antibiotic duration: protocol adherence was 82% in the**
256 **experimental group & 72.7% in the control group in the STOP IT trial, 79% & 82% in the**
257 **two arms in the DURAPOP trial [4, 5]. Non adherence was mostly associated with antibiotics**
258 **durations being outside accepted ranges, extending these beyond 24 hours would increase**
259 **adherence and not detract from the overall treatment allocations.**

260 We identified aspects of the protocol that reduced recruitment. The definition of cIAI used in
261 this study was more inclusive than recommended definitions as it allowed surgeons to make
262 a diagnosis of cIAI without operative evidence, thus allowing inclusion of patients who do not
263 undergo a source control procedure [9]. However, the definition used for cIAI in this trial
264 excluded 48% of patients who were treated for cIAI because they did not have both a recorded
265 fever ($\geq 38^{\circ}\text{C}$) and a neutrophilia ($>7.5 \times 10^9/\text{L}$). In a definitive trial, a more pragmatic definition
266 should be adopted to ensure evidence is gained for a more representative population of
267 patients treated for cIAI. Additionally, it was noted **other infections e.g. urinary tract or**
268 **respiratory tract infection**, not including cIAI relapses, were common, and consideration to
269 these being included within a primary outcome measure in a definitive trial would be needed.
270 **This study was not designed to detect a clinically significant difference in the**
271 **secondary outcomes, however we found that relapses predominantly occurred in**
272 **patients who had post-operative cIAs who received short course antibiotics. Thus,**
273 **supporting further research into our hypothesis that longer antibiotic durations may**
274 **reduce relapse rates.**

275 Complicated intra-abdominal infections continue to be associated with significant morbidity
276 and mortality. This trial demonstrates the feasibility of a substantive RCT to further investigate
277 antibiotic durations for the management of cIAs.

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279 Hospitals Trust; Catherine Moriarty, Senior Research Sister, Leeds Teaching Hospitals NHS
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282 **Compliance with Ethical Standards**

283 **Conflicts of interest:** The authors declare that they have no conflict of interest.

284 **Ethical approval:** All procedures performed in studies involving human participants were in
285 accordance with the ethical standards of the institutional and/or national research committee
286 and with the 1964 Helsinki declaration and its later amendments or comparable ethical
287 standards.

288 **Informed consent:** Informed consent was obtained from all individual participants included in
289 the study.

290 **Data availability:** The datasets generated during and analysed during the current study are
291 available from the corresponding author on reasonable request.

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Tables and figures

Table 1. Characteristics of patients who consented to participate and those who declined

	Consented (n 31)	Declined (n 32)
Age (years)	61.0 (45.0-72.0)	60.5 (48.3-79.3)
Females	11/31 (35.5%)	17/32 (53.1%)
Charlson score	4 (1-5)	4 (1.3-5)
HDU/ICU Admission	4/31 (12.9%)	8/32 (25.0%)
Post-operative infection	14/31 (45.2%)	13/32 (40.6%)
Presence of a perforated viscus	13/31 (41.9%)	13/32 (40.6%)
Data are median (IQR) or n/total (%)		

Table 2. Baseline characteristics of patients in each study arm

	Long course group, n=13	Short course group, n=17
Age (years)	60.0 (46.5-74.5)	63.0 (46.0-72.0)
Female	5/13 (38.5%)	6/17 (35.3%)
Charlson score	4 (1.5-8.5)	4 (1-5)
HDU/ICU Admission	2/13 (15.4%)	2/17 (11.8%)
Post-operative infection	4/13 (30.8%)	10/17 (58.8%)
Perforated viscus	7/13 (53.8%)	5/17 (29.4%)
Presence of a collection	8/13 (61.5%)	14/17 (82.4%)
Anastomotic leak	1/13 (7.7%)	4/17 (23.5%)
Site of cIAI		
Appendix	0/13 (0%)	1/17 (5.9%)
Biliary	1/13 (7.7%)	0/17 (0%)
Colon	5/13 (38.5%)	7/17 (41.2%)
Small bowel	3/13 (23.1%)	1/17 (5.9%)
Other	4/13 (30.8%)	7/17 (41.2%)
Gastro-oesophageal	0/13 (0%)	1/17 (5.9%)
Baseline health status [°]	35.0 (20.0-50.0)	30.0 (20.0-40.0)
NEWS* at diagnosis	3.0 (2.0-4.0)	3.0 (1.5-6.0)
C-reactive protein (mg/L) at diagnosis	220.0 (88.5-276.0)	218.0 (124.0-290.0)
Neutrophil count (10 ⁹ /L) at diagnosis	13.0 (9.2-15.2)	12.8 (9.4-19.2)
Temperature at diagnosis °C)	38.3 (38.2-38.5)	38.3 (37.8-38.7)
Source control procedure		
Percutaneous drainage	3/13 (23.1%)	7/17 (41.2%)
Surgical	8/13 (61.5%)	4/17 (23.5%)
Nil	2 (15.4%)	6/17 (35.3%)
Samples [∞] sent for culture	11/13 (84.6%)	16/17 (94.1%)
Antibiotic regimen altered due to drug resistant bacteria	3/11 (27.2%)	4/16 (25.0%)
Data are median (IQR) or n/total (%).		

[°]Measured by patient self-reported rating (EQ5D-VAS) on own overall health, scale from 0 (worst possible health) to 100 (best possible health). *National Early Warning Score. [^]data missing in 1/13 in LC arm and 1/17 in SC arm. [∞]Samples include blood cultures or pus cultures obtained intra-operatively/percutaneously

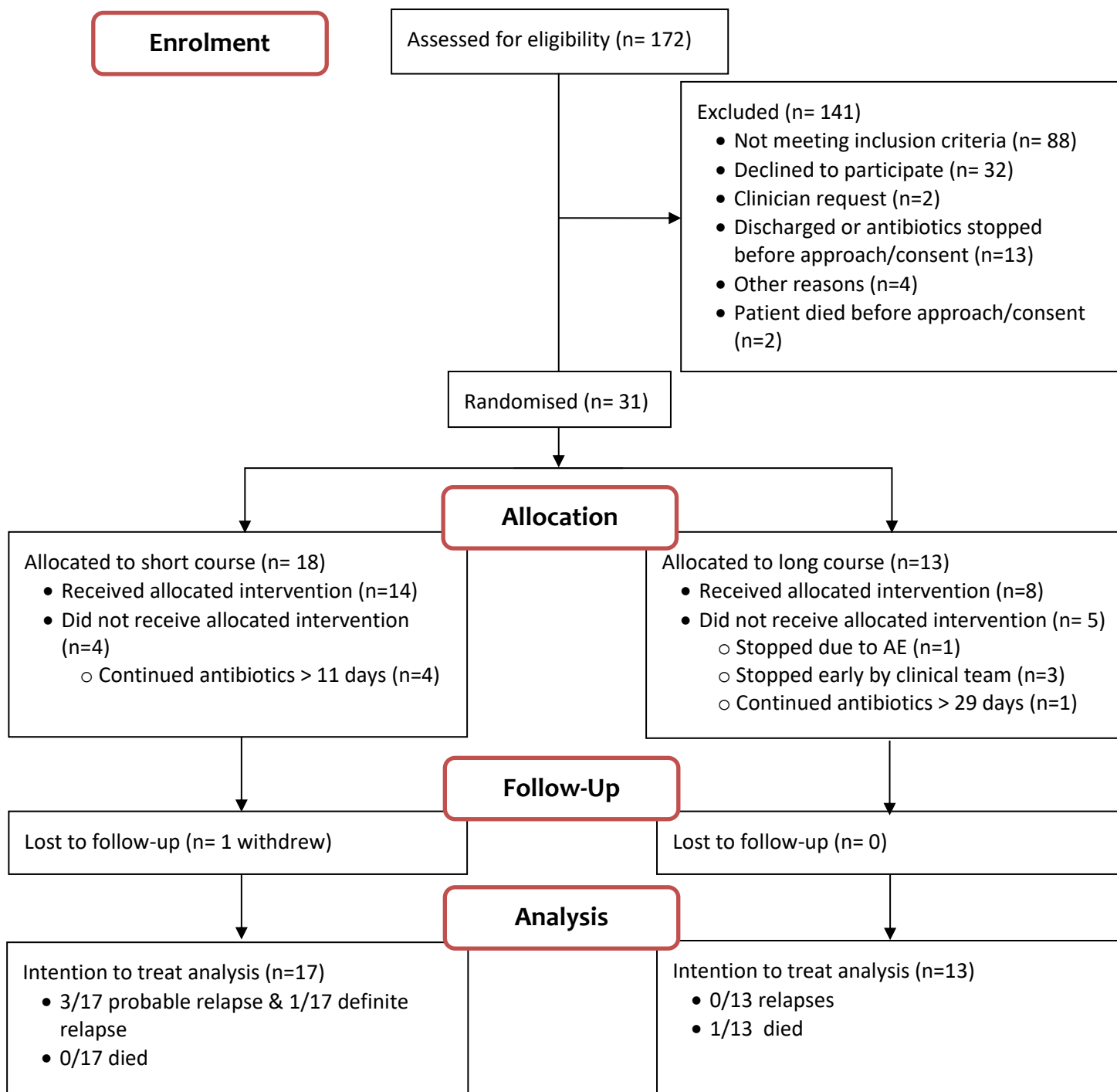
Table 3. Clinical outcomes (ITT analysis) at 90 days

	Total	Long course group	Short course group
Antibiotic duration (days) for cIAI	11.5 (8.0-28.0)	28 (17.5-28.0)	9 (7.5-11.5)
Relapse	4/30 (13.3%)	0 (0%)	4/17 (23.3%)
Death	1/30 (3%)	1/13 (7.7%)	0/17
Total antibiotic consumption (days) within 90 days of cIAI diagnosis	19 (9.8-28.0)	28 (17.5-30.0)	15 (8.5-26.0)
Length of stay (days) following cIAI diagnosis	8.5(4.8-17.8)	8.0 (4.5-11.0)	9.0 (4.5-31.0)
Number of source control procedures required for the management of cIAI	1 (0.8-1)	1 (1-1)	1 (0-1)
Data are median (IQR) or n/total (%)			

	Relapse (n = 4)	No relapse (n = 26)
Age (years)	65.5 (49.5-83.0)	61.0 (45.8-72.0)
Female	3/4 (75%)	8/26 (30.8%)
Median Charlson score (IQR)	4.0 (1.5-8.0)	4.0 (1.0-5.3)
Post-operative infection	3/4 (75.0%)	11/26 (42.3%)
Presence of a perforated viscus	1/4 (25%)	11/26 (42.3)
Presence of a collection(s)	3/4 (75%)	19/26 (73.0%)
Anastomotic leak	1/4 (25%)	4/26 (15.4%)
NEWS* at diagnosis	3.0 (0.5-6.8)	3.0 (2.0-5.3)
Source control procedure		
Percutaneous drainage	1/4 (25%)	7/ 26 (26.9%)
Surgical	2/4 (50%)	9/26 (34.6%)
Nil	1/4 (25%)	10/26 (38.5%)
Site of cIAI		
Appendix	0/4 (0%)	1/26 (3.8%)
Biliary	0/4 (0%)	1/26 (3.8%)
Colon	2/4 (50.0%)	10/26 (38.5%)
Small bowel	1/4 (25%)	3/26 (11.5%)
Other	1/4 (25%)	10/26 (38.5%)
Gastro-oesophageal	0/4 (0%)	1/26 (3.8%)
Antibiotic regimen altered due to presence of resistance	2/4 (50%)	5/26 (19.2%)
Data are median (IQR) or n/total (%). * National Early Warning Score		

Table 4.

Characteristics of patients who had a cIAI relapse



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352 Figure 1. Participant enrolment, allocation, follow-up and analysis

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