Study, country
Gacci, 2006
Italy
Study type, study period
Observational study.
Study period not reported.
Number of patients
19
Patient characteristics

Inclusion criteria: patients with T1G3 bladder tumour who did not respond to two 6-week courses of BCG.

Baseline characteristics:

	GEM (N = 9)	BCG (N = 10)
Male	7	8
Mean age, yrs	75	73.6
Median time from last recurrence, months	7	7
Median tumour diameter, cm	1	1.5

Intervention
Induction course: 6-week administration of gemcitabine (2,000 mg/50 ml) retained in the bladder for at least one hour. Maintenance therapy: gemcitabine as above once weekly for 3 consecutive weeks at 3, 6, 12 and 24 months.
Comparison
Induction course: 6-week administration of BCG (Tice strain, 2ml, 5 x 10^8 CFU, diluted in 50 ml) retained in the bladder for at least one

hour.

Maintenance therapy: single instillation as above at 3, 6, 12 and 24 months.

| **Length of follow-up** |
| Median 20 months (GEM group: 19 months, BCG group, 20 months) |

| **Outcome measures and effect size** |
| Tumour recurrence after treatment: |
| 6/9 (GEM) vs 5/10 (BCG). |

Tumour progression after treatment:
2/9 (GEM) vs 4/10 (BCG)

Mean time to recurrence:
6.5 months (GEM) vs 8.2 months (BCG)

Mean time to progression:
8.5 months (GEM) vs 5.5 months (BCG)

Incidence of adverse events:
2/9 (GEM, one urinary irritation, one fever) vs 3/10 (BCG, two fever, one haematuria).

Bladder preservation rate:
7/9 (GEM) vs 6/10 (BCG)

Overall survival:
9/9 (GEM) vs 8/10 (BCG)

| **Source of funding** |
| Not reported |

| **Risks of bias** |
| Selection bias: unclear/unknown risk. Method of allocation to treatment not reported. |

Performance bias: high risk. Method for selection of controls is not reported, but it is assumed that a historical control group was used.

Attrition bias: unclear/unknown risk. Participant flow not reported.

Detection bias: unclear/unknown risk. Reliability of measurement and reporting of outcomes is not clear. Outcomes are defined in study methods, but used ambiguously in the reporting of the results.

| **Additional comments** |
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