# Safety & tolerability

# Telavancin has a similar tolerability profile to vancomycin for Hospital Acquired Pneumonia due to Gram-positive pathogens[1]

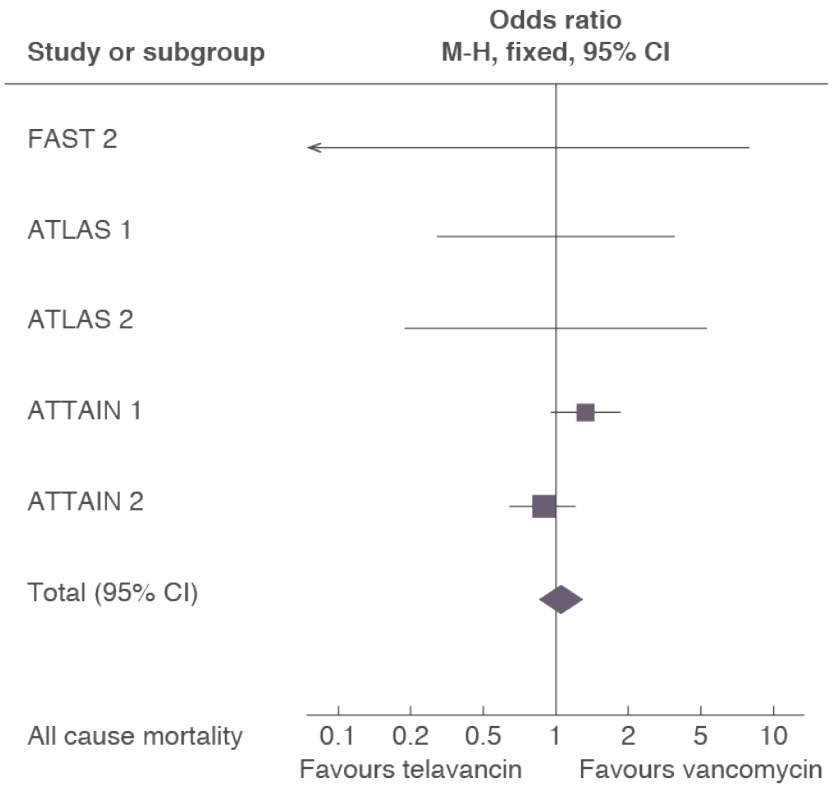
**Overview of adverse events (AE) – pooled studies (safety population)[1]**

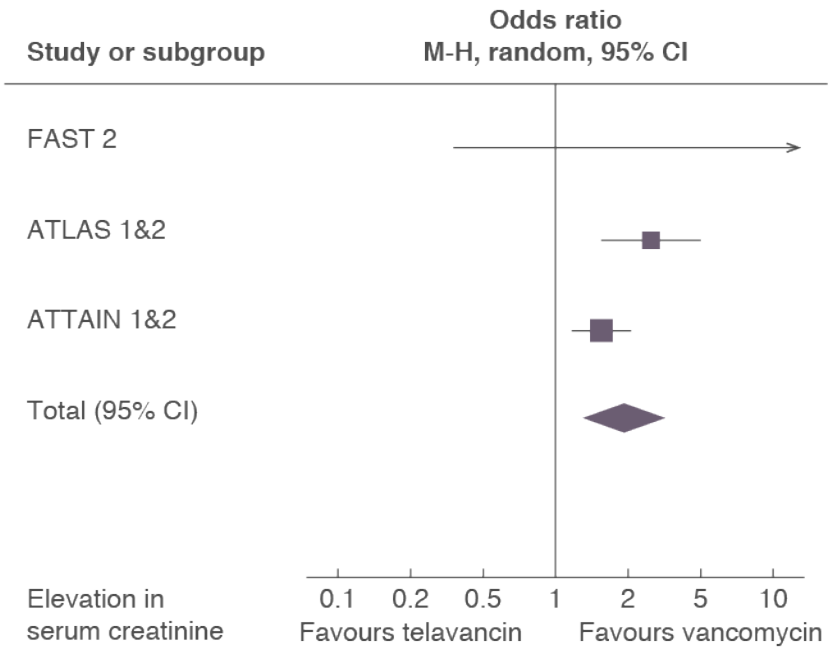
| Safety parameter | No. (%) of patients | |
|---|---|---|
| | Telavancin group (n=751) | Vancomycin group (n=752) |
| Death | 150 (20.0) | 140 (18.6) |
| Any TEAE | 616 (82) | 613 (82) |
| Any serious AE | 234 (31) | 197 (26) |
| Discontinued medication due to TEAE | 60 (8) | 40 (5) |
| TEAE ≥ 5% in any treatment arm | | |
| Diarrhoea | 85 (11) | 92 (12) |
| Renal impairment | 74 (10) | 57 (8) |
| Anaemia | 64 (9) | 85 (11) |
| Constipation | 70 (9) | 71 (9) |
| Hypokalemia | 61 (8) | 80 (11) |
| Hypotension | 48 (6) | 52 (7) |
| Nausea | 40 (5) | 31 (4) |
| Decubitus ulcer | 39 (5) | 44 (6) |
| Insomnia | 34 (5) | 47 (6) |
| Peripheral oedema | 34 (5) | 38 (5) |

TEAE, treatment-emergent AE.

**1.** Rubinstein E *et al. Clin Infect Dis* 2011; **52**(1): 31–40.

# Odds ratios of adverse events with telavancin versus vancomycin in cSSTIs and HAP.




FAST = Phase II cSSTI ATLAS = Phase III cSSTI ATTAIN = Phase III HAI

This data is from the total safety data base for telavancin and reflects all the infectious indications investigated. cSSSI is not a registered indication for telavancin in the EU[1]

**Patients with severe renal impairment or pre-existing acute renal failure are at greater risk of renal adverse effects when receiving telavancin than they would be with vancomycin[2]**

cSSTI, complicated skin and soft tissue infections; HAI, hospital acquired infections

**1.** Polyzos *et al.* PLoS One 2012; **7**(8): e41870. Epub 2012 Aug 16. 2. Torres A et al. J Antimicrob Chemother 2014; 69(4): 1119–26.

# Patients with renal impairment require dose adjustments of telavancin[1]

**Dosing in patients with renal impairment[1]**

| Creatinine clearance (CrCl; mL/min) | Dose adjustment | Recommended telavancin dose |
|---|---|---|
| >50 | None | 10 mg/kg every 24 hours |
| 30-50 | Reduce dose | 7.5 mg/kg every 24 hours |
| <30, including patients undergoing haemodialysis | Contraindicated | Contraindicated |

- Initial doses should be given according to calculated or measured CrCl as presented in the table above[1]
- During treatment, dose adjustments according to the table should be based on calculated or measured CrCl in patients with clinically relevant changes in renal function[1]

**1.** Telavancin SmPC, 2013.

# Telavancin and vancomycin have a comparable QTcF AE profile[1]

**ECG abnormalities – pooled studies (safety population)[1]**

| | Telavancin group (%) | Vancomycin group (%) |
|---|---|---|
| Prolongation of QTcF >60 msec | 8 | 7 |
| Maximum QTcF interval >500 msec | 2 | 2 |

- Prolongation of QTcF occurred in similar numbers of telavancin-treated and vancomycin-treated patients
- None of the patients experienced arrhythmias attributable to a prolonged QTcF interval

AE, adverse events; QTcF, Fridericia-corrected QT interval.

**1.** Rubinstein E *et al. Clin Infect Dis* 2011; **52**(1): 31–40.