

Landirolol Infusion Protocol Compliance

Maintaining staff training and awareness in a trial with a low recruitment target can be particularly challenging. On STRESS-L we have found that this has contributed to several events where the landiolol infusion is not administered in line with the trial protocol. We have produced this document to provide help provide guidance and ideas on effective methods to train and raise awareness for the trial.

Figure 1: Time of day when landiolol infusion non-compliance occurred

- All 6 protocol violations have occurred overnight as a result of the bedside nurses incorrectly titrating Landiolol and not following the Landiolol infusion protocol as presented in Figure 1.

LEARNING POINT: This emphasises the importance of a clear, effective handover of the IMP management from the research team to the bedside nursing team.

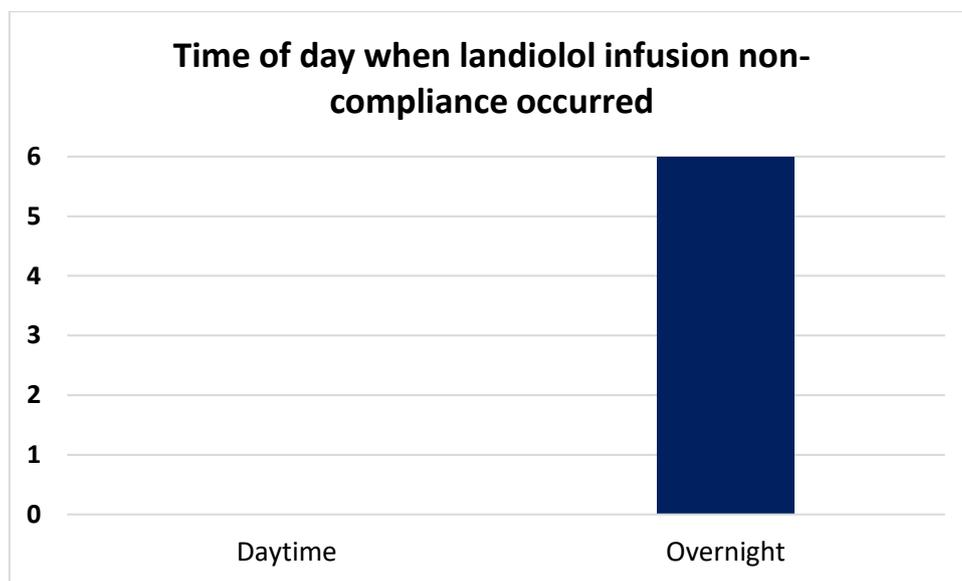
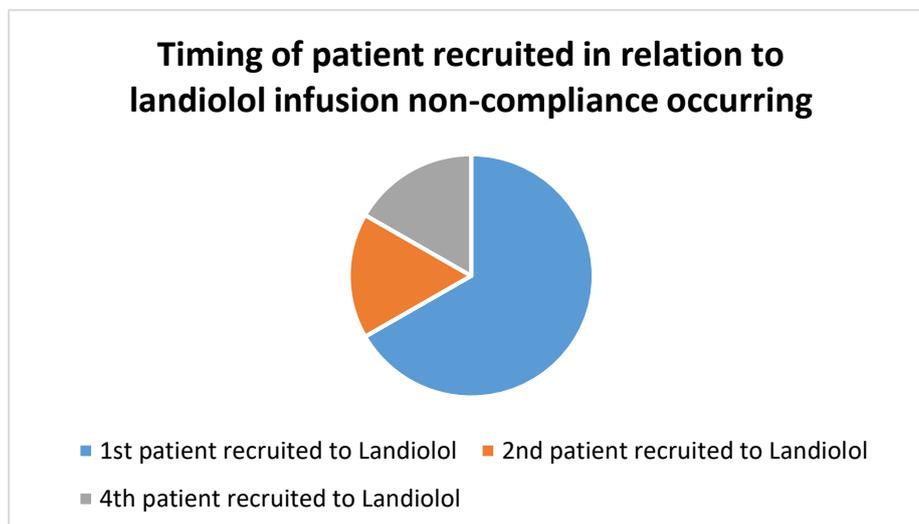


Figure 2: Timing of patient recruited in relation to landiolol infusion non-compliance occurring

- 4 of the protocol violations occurred when the 1st patient was randomised to Landiolol.
- 1 of the protocol violations occurred when the 2nd patient was randomised to Landiolol.
- 1 of the protocol violations occurred when the 4th patient was randomised to Landiolol as presented in Figure 3.



LEARNING POINT: Figure 2 highlights how errors usually occur following recruitment of the first trial participant to the landiolol arm of the study. The often lengthy delay following SIV and initial staff training to actually recruiting a participant and administering IMP pose a challenge to maintaining adequate training of the wider nursing pool.

There have, however, been 2 violations that have taken place in subsequent patients recruited to the landiolol arm – awareness of the study and training on IMP management should be an **ongoing process**.

CASE STUDY

A patient was recruited to the landiolol + standard care arm of the trial and the IMP infusion started in line with the infusion protocol to manage heart rate. Several days later the patient remained on minimum dose of 1 mcg/kg/min to maintain the patient heart rate within the target range and the infusion management was handed over to the bedside nursing team.

A secondary handover was later given and the overnight nursing team took over the IMP management. During this period the patient's heart rate fell below 80 bpm for an extended period but the landiolol infusion was not weaned. A brief episode of bradycardia was experienced and the team then acted appropriately to wean the landiolol infusion.

Following this event, extensive retraining was performed with the bedside nursing team. The research team and coordinating team implemented a number of preventative actions, some of which are listed below.

Suggested preventative actions

- Conduct 1:1 handovers between research nurses and ICU staff to ensure landiolol infusion protocol is understood
- Ideally, research nurse stay until overnight ICU staff arrive to conduct handover
- Ring overnight staff once handover complete and if possible during the weekend to reinforce landiolol infusion protocol
- Send monthly group emails and newsletters to ICU staff to keep momentum for the trial going
- Reminder of trial in medical handover checklist and nursing safety briefs
- Set alarms on monitors to alert ICU staff when patients heart rate is below 80 bpm
- Advert and information for STRESS-L on staff intranet page
- Display posters in ICU staff areas

Current memory aids and training materials available from Warwick CTU

- Presentation slides for training non-delegated ICU staff
- Landiolol Infusion Dosing charts with added instruction regarding ml/hr to mcg/kg/min conversion and do not exceed max dose of 40mcg/kg/min
- Posters for ICU staff areas to assist with screening and landiolol infusion guidance
- Noradrenaline and Landiolol Infusion flowcharts
- Excel spreadsheet which calculates Landiolol dose when weight is entered
- Patient enrolment stickers
- Do not use other beta blocker stickers
- Pens, travel mugs, sticky notes, stress balls

If you have any other ideas or training material requests please do not hesitate to get in touch
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