SAFETY PHARMACOLOGY

Telemetry

Telemetry in conscious and unrestrained animals is recommended by the ICH Guideline S7A[1] to assess safety pharmacology along the drug development process. Changes in systolic blood pressure, diastolic blood pressure, heart rate, electrocardiogram (ECG) and body temperature can be measured in order to predict any potential adverse cardiovascular effects of new drugs in non-clinical development.

Test System: *Rattus norvegicus* (Sprague-Dawley)

Number of animal per group: upon request

Route of administration: upon request

Treatment mode: upon request

Main read-outs: Systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, electrocardiogram and body temperature

Alternative read-outs: Exploratory activity

Validation Data

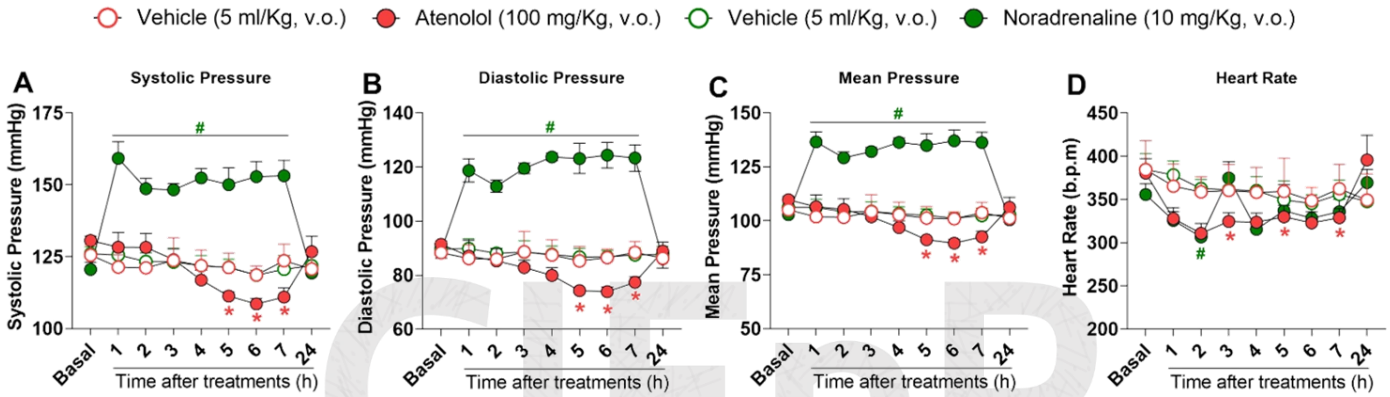

Figure 1. Evaluation of systolic blood pressure, diastolic blood pressure, mean blood pressure and heart rate of conscious and free-moving rats treated orally with vehicle (5 ml/kg), atenolol (100 mg/kg) or noradrenaline (10 mg/kg). Baseline values for each of the parameters were obtained before each treatment. Subsequently, each parameter was recorded at 1, 2, 3, 4, 5, 6, 7 and 24 hours after treatments. Two-way analysis of variance (ANOVA) followed by Dunnett's post hoc test were performed. Each point represents the mean ± S.E.M. * indicates a statistically significant difference when compared to the respective baseline value.

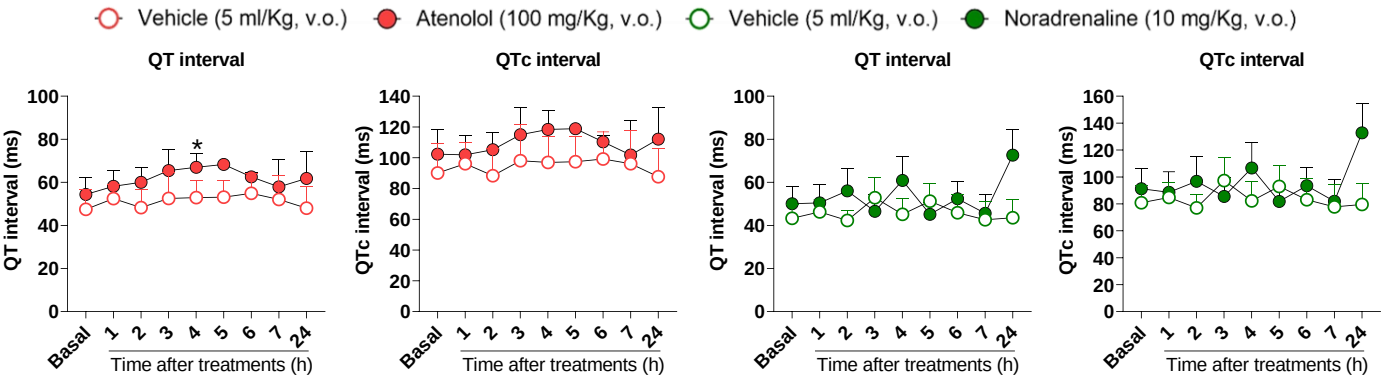

Figure 2. ECG parameters (QT interval and QTc interval) of conscious and free-moving rats treated orally with vehicle (5 ml/kg), atenolol (100 mg/kg) or noradrenaline (10 mg/kg). Baseline values were obtained before each treatment. Subsequently, each parameter was recorded at 1, 2, 3, 4, 5, 6, 7 and 24 hours after treatments. Two-way analysis of variance (ANOVA) followed by Dunnett's post hoc test were performed. Each point represents the mean ± S.E.M. * indicates a statistically significant difference when compared to the respective baseline value.

To avoid bias and to allow reproducibility all *in vivo* experiments follow the ARRIVE guidances[2]. Rat colony from Charles River Laboratories are breed and maintained in SPF conditions. The project includes study plan and final report. Raw data are inspected by quality assurance unity. The experimental procedures was previously approved by the CIEnP Committee on the Ethical Use of Animals.

References:
[1]ICH S7A: Safety Pharmacology Studies for Human Pharmaceuticals - S7A. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Current Step 4 version. 2000.

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