

Figure 3: Trial Flow for the Individual Patient

The trial consists of a Pre-treatment Period during which Screening, Baseline assessments and Randomization will be performed, a Treatment Period (Day 1 to Day 3) during which the patient will receive a daily 1-hour continuous IV infusion of trial drug, and a Follow-up Period (Day 4 to Day 180) during which follow-up assessments will be performed.

Abbreviations: h = hour; ICF = informed consent form.