**Schedule of the study visits and procedures**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study procedures** | **Screening** | | **Visit 1 (in-patient)** | | | | | | | | **Out-patient** | |
| **Visit 2** | **Visit 3 / Study end visit** |
| **Treatment administration 1** | **Follow-up** | |  | **Treatment administration 2** | **Follow-up** | |  |
| Study day | -3 to -1 |  | 1 | 2, 4, 7 | 3, 5, 6 | | 8 | 9, 11, 14 | 10, 12, 13 | | 21 (± 1) | 28 (± 1) |
| Informed consent | Х | |  |  |  | |  |  |  | |  |  |
| Demographic characteristics and medical history | Х | |  |  |  | |  |  |  | |  |  |
| Weight and height measurement, calculation of body mass index | Х | | Х |  |  | | Х |  |  | | Х | Х |
| Documentation of the surgery | Х | |  |  |  | |  |  |  | |  |  |
| Past and concomitant treatment | Х | | Х | Х | Х | | Х | Х | Х | | Х | Х |
| Complaints | Х | | Х | Х | Х | | Х | Х | Х | | Х | Х |
| Inclusion / non-inclusion criteria | Х | | Х |  |  | |  |  |  | |  |  |
| Physical examination | Х | | Х | Х | Х | | Х | Х | Х | | Х | Х |
| Vital signs | Х | | Х | Х | Х | | Х | Х | Х | | Х | Х |
| ECOG score | Х | |  |  |  | |  |  |  | |  |  |
| 12-lead ECG | Х | |  | Х |  | |  | Х |  | |  | Х |
| EchoCG | Х | |  | Х |  | |  | Х |  | |  |  |
| Hematology | Х | | Х | Х |  | |  | Х |  | | Х | Х |
| Clinical chemistry | Х | | Х | Х |  | |  | Х |  | | Х | Х |
| Coagulation test | Х | | Х | Х |  | |  | Х |  | | Х | Х |
| Urine analysis | Х | | Х | Х |  | |  | Х |  | | Х | Х |
| Pregnancy test (for women with reproductive potential) | Х | |  |  |  | |  |  |  | |  |  |
| Treatment administration |  | | Х |  |  | | Х |  |  | |  |  |
| AE/SAE collection | Х | | Х | Х | Х | | Х | Х | Х | | Х | Х |
| Exclusion criteria |  | | Х | Х | Х | | Х | Х | Х | | Х | Х |

AE, adverse event; ECG, electrocardiography; EchoCG, echocardiography; SAE, serious adverse event