

Supplementary Table 1. Adverse events

|                                           | Experimental group (N=128) |          |          | Control group (N=129) |          |          |
|-------------------------------------------|----------------------------|----------|----------|-----------------------|----------|----------|
| Term                                      | Number                     | Subjects | Rate (%) | Number                | Subjects | Rate (%) |
| <b>Total number of adverse events</b>     | 43                         | 30       | 23.44    | 47                    | 29       | 22.48    |
| <b>Metabolic and nutritional diseases</b> | 3                          | 3        | 2.34     | 2                     | 2        | 1.55     |
| Hypoproteinemia                           | 2                          | 2        | 1.56     | 0                     | 0        | 0.00     |
| Hypokalemia                               | 1                          | 1        | 0.78     | 1                     | 1        | 0.78     |
| Hyperlipidemia                            | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| <b>Ear and labyrinth diseases</b>         | 2                          | 2        | 1.56     | 0                     | 0        | 0.00     |
| Vertigo                                   | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Tympanitis                                | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| <b>Infectious and invasive diseases</b>   | 3                          | 3        | 2.34     | 1                     | 1        | 0.78     |
| Lung infections                           | 2                          | 2        | 1.56     | 0                     | 0        | 0.00     |
| Genitourinary tract infections            | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| Fungal otitis externa                     | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| <b>All kinds of checks</b>                | 15                         | 12       | 9.38     | 18                    | 14       | 10.85    |
| Decreased heart rate                      | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Decreased blood potassium                 | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| Elevated blood glucose                    | 3                          | 3        | 2.34     | 3                     | 3        | 2.33     |
| Increased blood pressure                  | 11                         | 10       | 7.81     | 14                    | 13       | 10.08    |
| <b>Various neurological disorders</b>     | 5                          | 5        | 3.91     | 4                     | 4        | 3.10     |
| Transient ischemic attack                 | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Aphasia                                   | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| Headache                                  | 4                          | 4        | 3.13     | 1                     | 1        | 0.78     |

|                                                                       | Experimental group (N=128) |          |          | Control group (N=129) |          |          |
|-----------------------------------------------------------------------|----------------------------|----------|----------|-----------------------|----------|----------|
| Term                                                                  | Number                     | Subjects | Rate (%) | Number                | Subjects | Rate (%) |
| Dizzy                                                                 | 0                          | 0        | 0.00     | 2                     | 2        | 1.55     |
| Various injuries, poisoning and surgical complications                | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Painful incision                                                      | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Various musculoskeletal and connective tissue diseases                | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| Pain in the lower back or ribs                                        | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| Respirational, thoracic, and mediastinal disorders                    | 1                          | 1        | 0.78     | 1                     | 1        | 0.78     |
| Asthma                                                                | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| Cough                                                                 | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Psychosis                                                             | 2                          | 2        | 1.56     | 4                     | 3        | 2.33     |
| Insomnia                                                              | 1                          | 1        | 0.78     | 3                     | 3        | 2.33     |
| Difficulty falling asleep                                             | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Restlessness                                                          | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| Diseases of the skin and subcutaneous tissue                          | 2                          | 2        | 1.56     | 1                     | 1        | 0.78     |
| Erythema                                                              | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Rash                                                                  | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |
| Eczema                                                                | 1                          | 1        | 0.78     | 0                     | 0        | 0.00     |
| Systemic diseases and various reactions at the site of administration | 1                          | 1        | 0.78     | 2                     | 2        | 1.55     |
| Fever                                                                 | 1                          | 1        | 0.78     | 1                     | 1        | 0.78     |
| Chest discomfort                                                      | 0                          | 0        | 0.00     | 1                     | 1        | 0.78     |

|                                                   | Experimental group (N=128) |          |             | Control group (N=129) |           |          |
|---------------------------------------------------|----------------------------|----------|-------------|-----------------------|-----------|----------|
| Term                                              | Number                     | Subjects | Rate (%)    | Number                | Subjects  | Rate (%) |
| <b>Diseases of the kidneys and urinary system</b> | 0                          | 0        | 0.00        | 1                     | 1         | 0.78     |
| Oliguria                                          | 0                          | 0        | 0.00        | 1                     | 1         | 0.78     |
| <b>Diseases of the gastrointestinal system</b>    | 7                          | 7        | 5.47        | 7                     | 6         | 4.65     |
| Constipation                                      | 3                          | 3        | 2.34        | 2                     | 2         | 1.55     |
| Bloating                                          | 0                          | 0        | 0.00        | 2                     | 2         | 1.55     |
| Vomit                                             | 2                          | 2        | 1.56        | 3                     | 3         | 2.33     |
| Dyspepsia                                         | 1                          | 1        | 0.78        | 0                     | 0         | 0.00     |
| Stress ulcers                                     | 1                          | 1        | 0.78        | 0                     | 0         | 0.00     |
| <b>Heart disease</b>                              | 3                          | 2        | 1.56        | 0                     | 0         | 0.00     |
| Palpitation                                       | 2                          | 2        | 1.56        | 0                     | 0         | 0.00     |
| Heart discomfort                                  | 1                          | 1        | 0.78        | 0                     | 0         | 0.00     |
| <b>Vascular and lymphatic diseases</b>            | 2                          | 2        | 1.56        | 0                     | 0         | 0.00     |
| Hypertension                                      | 1                          | 1        | 0.78        | 0                     | 0         | 0.00     |
| Thrombosis                                        | 1                          | 1        | 0.78        | 0                     | 0         | 0.00     |
| <b>Diseases of the blood system</b>               | 0                          | 0        |             | 1                     | 1         | 0.78     |
| Anaemia                                           | 0                          | 0        |             | 1                     | 1         | 0.78     |
|                                                   |                            |          |             |                       |           |          |
| <b>Total subjects of adverse events</b>           |                            |          |             |                       |           |          |
| No. of cases (No. missing)                        | 128 (0)                    |          | 129 (0)     |                       | CHI2=0.03 | P=0.8553 |
| No n(%)                                           | 98 (76.56)                 |          | 100 (77.52) |                       |           |          |
| Yes n(%)                                          | 30 (23.44)                 |          | 29 (22.48)  |                       |           |          |