

Description of the randomization process:

Randomization was performed before start of the study, using a free randomization tool (www.randomizer.org). Output of the randomizer was transferred into envelopes by a layperson, marked with consecutive numbering (1-32) on the outside, and sealed. Moment of enrolment in the study, determined which envelop was opened on the day of the intervention (e.g. the third enrolled patient was linked to envelop 3). The whole procedure was performed in duplicate, for reasons of safety and emergency de-blinding in case of a (serious) adverse event during the study. The duplicate set of envelopes was held by an independent layperson during the study. Blinding remained until handover of all gathered data to an independent statistician had taken place.