

# CLINICAL STUDY

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## MOBILITY AID SYSTEM **s.a.m** ERGONOM

Clinical study NCT01746433  
Patent No. EP2617403-24/07/2013

### METHOD

- A prospective, single-centre, randomised study comparing two medical devices (SAM Ergonom versus lifting column)
- Consenting patients, aged more than sixty-five years, with stable medical condition, without cognitive deficit
- Patients with difficulties in performing the “lying-sitting” transfers in less than ten seconds, with a postural balance of 2 out of 4<sup>1</sup>
- Positioning of the patient during the experiment: bedridden, centred pelvis, greater trochanter at the level of the joint of the headrest
- Two consecutive attempts: learning, timed observation phase
- Primary endpoint: successful transfer from a lying position to a sitting position
- Secondary endpoint: necessary time to sit down (min) and evaluation of the movement of the mass centre during the action of sitting
- Number of patients included: 38 namely 19 in the exposed group (SAM) and 19 in the control group
- Average age 84.7 (71; 93); Female/Male ratio 1.92

<sup>1</sup>Postural Balance Scale, Level 2 - Seated postural balance maintained without back support, but loss of balance if pushed, irrespective of the direction.

### RESULTS

The use of the SAM Ergonom device improves the “Lying-Sitting” recovery motor diagram of the patients included. SAM may influence the motor strategy during psychomotor regression syndrome by bringing the mass centre to an anterior rotation in 90% of the cases for the first five seconds (versus 50% in retropulsion among the patients using lifting columns).

#### ■ PRIMARY ENDPOINT: successful transfer

- SAM: success at **89.5%**
- Lifting column: success at 68%
- **Significant difference**

#### ■ SECONDARY ENDPOINT: time to sit down

- SAM: 12.5 seconds (4; 24)
- Lifting column: 12 seconds (5; 20)
- Non-significant difference

