CLINICAL TRIALS

METHOD

- Observational, non-interventional, multicentre Clinical Study; Descriptive analysis
- Date of study: 2007 to 2008. 40% Home care, 60% Local authorities. Sample size: 30 patients
- Average age 78 years; sex-ratio W/M 2,3; Initial average BMI 22,5 (13,8 ; 42,2); Initial average Karnofsky score 36%; Initial average Norton score: 8,47
- 48 pressure ulcers: 48% sacrum, 38% heels; 39% stage 1-2, 61% stage 3-4
- Main pathologies identified: cancerology, diseases of aging, orthopaedic states, neurology, pulmonary diseases
- Clinical state: 70% deterioration, 10% improvement, 20% stationary
- Assessment at D0, D10, D20, D30
- Effectiveness variables: state of the wound, measurements of volume and surface, distinction of viable and non viable tissue, proportion of exudate, clinical state

RESULTS

- MAIN JUDGEMENT CRITERIA: healing initiation of pressure ulcers which are getting worse
- Aid for the prevention and healing of stage 1 to 4 pressure ulcers

Healing gain
According to the respective methods of Kundin and Schubert
- surface gain: 0.44 cm² / day
- and/or volume gain: 0.86 cm³ / day