

Clinical studies on dietary management of pressure ulcers using Cubitan / Cubison

Cubitan and Cubison have unrivalled clinical evidence supporting their efficacy in dietary management of pressure ulcers

Table 1. Treatment studies with Cubitan / Nutrison Advanced Cubison

Reference	Study type	Population	Intervention	Results	Comments
Cereda et al, 2015	RCT	200 malnourished long-term care or home care patients with grade II, III and IV pressure ulcers	2 Cubitan (400 ml) daily for 8 weeks vs. 400 ml isocaloric, isonitrogenous formula	Use of Cubitan (n = 101) resulted in a greater reduction in PU area (mean reduction 60.9%) than with the control formula (n = 99) (45.2%) (p = 0.017). In Cubitan group, a more frequent reduction in area of 40% or greater at 8 weeks was also seen (odds ratio 1.98; p = 0.018).	The authors conclude that among malnourished patients with pressure ulcers, 8 weeks of supplementation with an oral nutritional formula enriched with arginine, zinc, and antioxidants (Cubitan) improved PU healing.
Van Anholt et al, 2010	RCT	43 non-malnourished institutionalised patients with grade III and IV pressure ulcers	3 Cubitan daily vs. non-caloric placebo	Cubitan treatment improved PU healing compared to control group. Cubitan treatment showed a significant difference in PU surface area (p=0.016) and PUSH score (p= 0.033) over time compared to the control group Cubitan treatment resulted in a significant change in wound size 2 weeks earlier than the control group (3 weeks compared to 5 weeks) Cubitan treatment showed significantly less dressings per week compared to control at weeks 3, 5, 6, and 7 (p<0.05) and less time spent on dressings at week 4 compared to controls (p=0.010)	The authors conclude that this study proves that non-malnourished patients with pressure ulcers can benefit directly from a specific nutritional supplement (Cubitan) and that the benefit of this supplement might reach beyond restoring caloric and protein deficiencies, as often is the case in malnourished patients
Cereda et al., 2009	RCT	28 institutionalised elderly with grade II-IV pressure ulcers	13 subjects received standard diet plus 2 Cubitan or Cubison daily and 15 subjects received standard nutrition (hospital diet or standard 16% energy from protein ONS) for a period of 12 weeks	Cubitan or Cubison reduced PU surface area significantly more than standard enteral formula after 8 (P<0.02) and 12 weeks (P<0.005) Cubitan or Cubison treatment reduced PUSH score significantly more than controls after 12 weeks (P<0.05) Cubitan or Cubison treatment and treatment with a standard enteral formula both resulted in significantly improved PU healing compared to baseline (P<0.001) after 12 weeks	The authors concluded that the rate of PU healing appears to accelerate when Cubitan or Cubison is administered, making such a formula preferable to a standard enteral formula, however further confirmation is required
Heyman et al., 2008	CT, single group	245 long-term care residents with grade II-IV pressure ulcers; mean age 82 y	2-3 times Cubitan daily for 9 weeks, along with their normal diet or enteral feed and standard pressure care	Cubitan treatment reduced average PU area from 1580±3743mm ² to 743±1809mm ² (P<0.0001) Cubitan treatment resulted in complete wound closure after 3 and 9 wks in 7% and 20% of patients Cubitan significantly reduced the amount of exudation (P<0.0001)	The authors concluded that a nutritional intervention Cubitan added to standard care resulted in a statistically significant reduction in pressure ulcer area of long-term care residents
Frías Soriano et al., 2004	CT, single group	39 elderly in-patients with pressure ulcers grade III-IV; mean age 75 y	2-3 Cubitan daily for 3 weeks, or standard enteral feed and standard pressure care	Cubitan treatment showed a 29% median reduction of PU area from 23.6cm ² to 19.2cm ² (P<0.001) in 3 weeks Cubitan treatment reduced the amount of exudate in infected ulcers by 60% (P=0.012) and incidence of necrotic tissue by 76% (P=0.001) in 3 weeks	Cubitan treatment showed significantly faster wound healing rate than high protein ONS when compared to historical controls The authors concluded that nutritional intervention in the form of a specific oral nutritional supplement rich in protein and enriched with arginine, vitamin C and zinc (Cubitan) resulted in a significant reduction in ulcer area and improvement in the wound condition in patients with grade III and IV pressure ulcers within three weeks
Benati et al., 2001	RCT, parallel groups	16 cognitively impaired elderly in-patients with pressure ulcers Aged 72 – 91y	2 Cubitan daily for 15 days vs. standard hospital diet vs. 2 x high protein ONS	Cubitan treatment resulted in the lowest PSST (Pressure Sore Status Tool) scores after 2 weeks Cubitan treatment and treatment with a high protein ONS had more effect on PU healing than treatment with a standard hospital diet	The authors concluded that this data supported the use of a nutritional supplement enriched with arginine, zinc and antioxidants (Cubitan), in patients with pressure ulcers The data were provided only graphically

RCT = randomised controlled trials; CT = clinical trial; PU = pressure ulcer.

Table 2. Health economic studies with Cubitan

Reference	Manuscript type	Description	Results
Cereda et al, 2017	Systematic review and meta-analysis	The cost analysis focused on: the difference in direct medical costs of local PU care between groups and incremental cost-effectiveness ratio of nutritional therapy related to significant study endpoints.	Although Cubitan was more expensive, its use resulted in money saving with respect to both non-nutritional PU care activities (difference, -113.7 Euros; p= 0.001) and costs of local PU care (difference, -74.3 Euros; p=0.013). Therefore, given its efficacy it proved to be a cost-effective intervention. The authors concluded that use of Cubitan not only results in better healing of PUs, but also reduces the costs of local PU care from a local healthcare system perspective.
Schols et al., 2003	Narrative review	Economic review assessing the actual costs of treating pressure ulcers and the potential cost into effectiveness of incorporating Cubitan in to patient care	Cubitan treatment was indicated to reduce the cost of pressure ulcer treatment if length of hospital stay is reduced by as little as one day, irrespective of pressure ulcer grade. The authors suggest that use of Cubitan is likely to reduce length of stay by more than one day, resulting in greater cost benefits.

Table 3. Review papers on Cubitan

Reference	Manuscript type	Description	Results
Cereda et al, 2017	Systematic review and meta-analysis	Review and meta-analysis of RCTs from 1-1997 until 10-2015. 3 RCTs.	Cubitan resulted in significantly higher reduction ulcer area (-5.7%; P=0.030) at 8 weeks. Cubitan resulted a higher proportion of participants having a 40% or greater reduction in PU size (OR=1.72; P=0.033) at 8 weeks. A nearly significant difference in complete healing at 8 weeks and the percentage of change in the area at 4 weeks was observed. The authors concluded that use of Cubitan for at least 8 weeks are associated with improved PU healing compared with standard formulas. The meta-analysis reasonably supports as Grade A evidence for the use of Cubitan in the nutritional support of PU patients.
Schols et al., 2009	Narrative review	Narrative review of studies investigating Cubitan up to October 2008	Cubitan treatment shows positive effects on pressure ulcer healing and may reduce the risk of developing pressure ulcers

Table 4. Cubitan study for the healing of chronic wounds

Reference	Study type	Population	Intervention	Results	Comments
Neyens et al, 2017	Case study series	29 non-malnourished patients with chronic wounds: diabetic foot ulcers (DFUs), arterial leg ulcers (ALUs), venous leg ulcers (VLUs) and pressure ulcers (PUs). (Wounds exists for at least 3 wks)	Overall 2 Cubitan (400 ml) daily for max 12 weeks.	Within 2 to 12 weeks use of Cubitan resulted in eight ulcers healed completely (3 DFUs, 3 VLUs, 4 PUs), thirteen ulcers showed clear signs of healing through decreased wound surface area ranging from 25% to 88% reduction (6 DFUs, 3 ALUs, 4 VLUs), and three ulcers kept unchanged (2 ALUs, 1 VLU). 3 PUs were lost to follow.	The authors conclude that nutritional support with Cubitan seems to be beneficial for the healing of different types of chronic wounds. The patients' compliance with the product was very high, and they rated it as good.

References

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Nutricia also offers Nutrison Advanced Cubison, the tube feed for treatment of patients with pressure ulcers



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