

The effect of specialized nutritional intervention with a disease-specific sip feed (Cubitan) in the support of patients with pressure ulcers.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20924

Source

Nationaal Trial Register

Brief title

CUBE study (Cubitan Efficacy study)

Health condition

Patients with stage III/IV pressure ulcers.

Sponsors and support

Primary sponsor: Numico Research B.V.

Source(s) of monetary or material Support: Numico Research B.V.

Intervention

Outcome measures

Primary outcome

To compare the effect of Cubitan added to standard institutional diet with non-caloric placebo

added to standard institutional diet on pressure ulcer size during 8 weeks.

Secondary outcome

To compare the effect of Cubitan added to standard institutional diet with non-caloric placebo added to standard institutional diet on pressure Ulcer Scale for Healing (PUSH) tool score and photographic assessment during 8 weeks (reflecting pressure ulcer size, exudate amount and tissue type).

Study description

Background summary

Pressure ulcers are an increasing problem in aging Western societies and this has a significant impact on the quality of life of patients and on health economics. The prevalence ranges from 1 to 18% of in-patients and from 3 to 28% of those admitted to long-term settings. One study showed a prevalence of pressure ulcers of 10.9% out of 1431 patients in 2 Dutch hospitals. These patients were admitted to surgical, internal, neurological and/or geriatric wards between January 1999 and June 2000.

Due to the high prevalence the economic consequences are substantial, according to the Dutch Inspection of Healthcare (Inspectie voor de Gezondheidszorg) the annual costs of decubitus in 2004 were estimated to be about half a billion euros due to required intensive treatment and prolonged institutional admission. Moreover, the costs of treating pressure ulcers increase with ulcer grade, because time to heal is longer and the incidence of complications is higher in severe cases. In the UK, for example, the mean cost of treating a pressure ulcer varied from £1,064 (grade I) to £10,551 (grade IV) per patient, respectively.

Cubitan (Nutricia N.V., The Netherlands) is a Food for Special Medical Purposes (FSMP) for the dietary management of pressure ulcers. This enteral clinical nutrition sip feed is specifically designed for patients with pressure ulcers and is high in energy and protein and enriched with nutrients that are essential for pressure ulcer healing.

Although the role of nutrition is being recognised and guidelines advice nutritional supplementation for patients with pressure ulcers, nutritional supplementation is not yet part of standard (pressure ulcer) care in every setting. Conventional pressure ulcer care in this population exists of applying dressings, anti-decubitus mattresses, side-to-side turning schedules and debridement. So far, there is a paucity of well-designed trials using appropriate control groups and relevant clinical outcomes that examine the efficacy of

supplemental nutrients on the healing of pressure ulcers. This study aims to investigate whether a nutritional product specifically designed to promote pressure ulcer healing will improve the rate of pressure ulcer healing in patients diagnosed with pressure ulcers stage III or IV.

Study objective

Improving the rate stage III/IV pressure ulcers heal through nutritional support.

Study design

N/A

Intervention

Group x: receiving standard institutional diet + daily 3 x 200 ml of Cubitan between meals for a maximum period of 8 weeks.

Group y: receiving standard institutional diet + daily 3 x 200 ml non-caloric placebo between meals for a maximum period of 8 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Stage III or IV pressure ulcers according to the European Pressure Ulcer Advisory Panel (EPUAP) classification system;
2. Stage III or IV pressure ulcers located on sacrum, greater trochanter, ischium or heel;
3. Age over 18 years and below 90 years;
4. Written informed consent from either patient or legal representative for patients who cannot consent themselves;
5. Use of standard institutional or regular diet without nutritional supplements during the last 2 weeks.

Exclusion criteria

1. Patients with severe medical conditions, e.g. ICU patients, patients with sepsis or serious infections, cancer patients requiring therapy, or patients after recent (< 3 months) myocardial infarction;
2. Patients with diabetes ulcers, ulcus cruris and/or vascular ulcer;
3. Life expectancy less than 6 months or hospice (palliative) care;
4. (Expected within 6 months) Nutrition via PEG (Percutaneous Endoscopic Gastrostomy) or PEJ (Percutaneous Endoscopic Jejunostomy) or nasogastric tube;
5. Drug or alcohol abuse in the opinion of investigator;
6. Patients prescribed medications that have an effect on pressure ulcer healing, e.g. hydroxyurea or chronic use of corticosteroids;
7. Protein-restricted diet due to renal insufficiency based on investigator's judgement;
8. BMI <18.5 for patients between 18 and 70 years; BMI <21 for patients over 70 years.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion	
Date:	05-12-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1119
NTR-old	NTR1154
Other	Numico Research B.V. : 100.029.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A