Evidence Table H-3b. Nutrition observational studies

| **Author year Country Overall Quality Rating** | **Study Type** | **Confounders assessed in analysis** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age Sex Race** | **Ulcer Type/ Severity at Baseline (Intervention Onset)** | **Treatment A** | **Treatment B** | **Treatment C** | **Duration of Followup** | **Study Setting** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Barnes, 200738 US Poor | Observational | Hypertension Cardiovascular disease  Paraplegia/ quadriplegia organic brain syndrome | Stage III-IV PU; chronically malnourished patients | Extremity decubital | NR/28/28/28 | Age (Mean): NR Female: NR Race: NR | Stages III and IV | Prealbumin levels of 18.0 to 45.0 mg/dL | NA | NA | ≥30 days | Hospital |
| Breslow, 199339 US Fair | Observational: non-randomized trial | Malnourished; dementia; cerebrovascular accident; anozic encephalopathy; spinal cord injury; Parkinson's disease | NPUAP Stage III-IV PU; malnourished; nutritional risk (Article reports Shea stage II-IV PU criteria) | Insulin dependent diabetes, renal failure, liver dysfunction, hematocrit <25%, chronic use of steroids;  cancer; significant gastrointestinal dysfunction | NR/48/48/28 | Age (Mean): 72 years  Female: 58% Race: NR | Total PU n=33  Treatment A  n=13 38% stage III 62% stage IV  Treatment B n=15  47% stage III 53% stage IV | 14% of total calories as protein (brand name Ensure, 1000 calories and 37 g protein/L) tube fed or as meal supplements | 24% of total calories as protein (brand name Sustacal, 1060 calories and 61g protein/L) tube fed or as meal supplements | NA | 8 weeks | Nursing home/long-term care facility |
| Brewer, 201040 Australia Fair | Observational: prospective | Spinal cord injury Paraplegic Quadriplegic | Spinal cord injury, 18+ years of age, residing in Melbourne metropolitan area and category II, III or IV PU | Phenylketonuria, Sepsis, Chronic renal failure, metabolic disease, diabetic foot ulcers and clinical suspicion of osteomyelitis, receiving hydroxyurea or greater than 10 mg prednisolone or 1.5 mg dexamethasone/ day | 68/35/35/35 | Age (Mean): 51 years,  Female: 3%  Race: NR | Treatment A PU n=30  Treatment B PU n=26 | Two sachets of commercially available argine-containing powder per day until full wound healing had been confirmed | Participants were compared to a historical comparator group. | NA | 10 months | Community |

| Evidence Table H-3b: Nutrition Observational Studies, continued |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Author year Country Overall Quality Rating** | **Study Type** | **Confounders assessed in analysis** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **Age Sex Race** | **Ulcer Type/ Severity at Baseline (Intervention Onset)** | **Treatment A** | **Treatment B** | **Treatment C** | **Duration of Followup** | **Study Setting** |
| Houston, 200141 US Fair | Observational | Older population | Older; institutionalized; under current PU treatment | NR | NR/NR/70/68 | Age (Mean): NR Female: NR Race: NR | Treatment A 84% stage II 16% stage III-IV  Treatment B 91% stage II 9% stage III-IV | Zinc sulfate (440mg/d, similar to 100mg elemental zinc/day) | Similar care, no oral supplements | NA | 30 days | Nursing home/long-term-care facility |
| Yamamoto, 200942 Japan Fair | Observational: retrospective | Malignant neoplasm Cerebral disease Orthopedic disease Cardiovascular disease Gastrointestinal disease Renal disease  Respiratory disease | Medical Center patients with either improved or worsened PU wounds | Discharged prior to PU healing or died within 1 month | NR/40/40/40 | Age (Mean): 69 years Female: NR  Race: NR | Treatment A: 38% stage I  62% stage II  Treatment B: 26% stage I  74% stage II | More than 30k cal/kg per day | Less than 20 kcal/kg per day | NA | 6 weeks | Hospital |

| **Evidence Table H-3b: Nutrition Observational Studies, continued** |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, year Country Overall Quality Rating** | **Outcomes: Complete Wound Healing** | **Outcomes: Wound Surface Area** | **Outcomes: Healing Time** | **Outcomes: Infection Rate** | **Outcomes: Osteomyelitis Rate** | **Outcomes: Recurrence Rate** | **Outcomes: Pain** | **Other Outcomes: Specify** |
| Barnes, 200738 US Poor | NR | Mean improvement of 0.82 cc reduction of wound volume per day | NR | NR | NR | NR | NR | NR |
| Breslow, 199339 US Fair | NR | Treatment A -2.1 cm2change from baseline to final  15% improvement  Treatment B-4.2cm2 change from baseline to final  (p<0.02) 15% improvement | Treatment A PU decreased by 2.1cm2 in 8 weeks  Treatment B PU decreased by 4.2 cm2 in 8 weeks | NR | NR | NR | NR | NR |
| Brewer, 201040 Australia Fair | Treatment A: 100% (n=30)  Treatment B: 100% (n=26) | NR | Treatment A: 11 weeks, mean healing time  Treatment B: 21 weeks mean healing time p=0.006 | NR | NR | NR | NR | NR |
| Houston, 200141 US Fair | NR | Improvement in volume of PU stages III or IV of intervention patients but not in stage II PU | NR | NR | NR | NR | NR | NR |
| Yamamoto, 200942 Japan Fair | 53% (n=21) of patients healed or improved | NR | 52% (n=21) of patients healed or improved in 6 weeks | NR | NR | NR | NR | NR |

| **Evidence Table  H-3b: Nutrition Observational Studies, continued** |  |  |  |  |  |  |  |  |  |
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| **Author, year Country Overall Quality Rating** | **Harms: Pain** | **Harms: Dermatologic Complications** | **Harms: Bleeding** | **Harms: Infection** | **Other Harms: Specify** | **Serve Adverse Events** | **Withdrawal due to Adverse Events** | **Overall Adverse Events Rate** | **Funding Source** |
| Barnes, 200738 US Poor | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Breslow, 199339 US Fair | NR | NR | NR | NR | NR | NR | NR | NR | Mean Johnson Nutritional Group, Francis Scott Key Medical Center General Clinical Research Center, Johns Hopkins Academic Teaching Nursing Home Award |
| Brewer, 201040 Australia Fair | NR | NR | NR | NR | NR | NR | NR | NR | The Eirene Lucas Foundation |
| Houston, 200141  US Fair | NR | NR | NR | Infection requiring antibiotics: Treatment A 28% (n=7)  Treatment B 5% (n=2) | NR | Nausea/vomiting Treatment A: 20% (n=5)  Treatment B: 2% (n=1) | NR | 22% (n=15) | NR |
| Yamamoto, 200942 Japan Fair | NR | NR | NR | NR | NR | NR | NR | NR | NR |