Evidence Table H-3b. Nutrition observational studies

| **Author yearCountryOverall Quality Rating** | **Study Type** | **Confounders assessed in analysis** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **AgeSexRace** | **Ulcer Type/ Severity at Baseline (Intervention Onset)** | **Treatment A**  | **Treatment B** | **Treatment C** | **Duration of Followup** | **Study Setting** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Barnes, 200738USPoor | Observational | HypertensionCardiovascular disease Paraplegia/ quadriplegiaorganic brain syndrome | Stage III-IV PU; chronically malnourished patients | Extremity decubital | NR/28/28/28 | Age (Mean): NRFemale: NRRace: NR | Stages III and IV | Prealbumin levels of 18.0 to 45.0 mg/dL | NA | NA |  ≥30 days | Hospital |
| Breslow, 199339USFair | 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 yearsFemale: 58% Race: NR | Total PU n=33Treatment An=1338% stage III62% stage IVTreatment Bn=1547% stage III53% 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, 201040AustraliaFair | Observational: prospective | Spinal cord injuryParaplegicQuadriplegic | 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 APU n=30Treatment BPU 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 yearCountryOverall Quality Rating** | **Study Type** | **Confounders assessed in analysis** | **Eligibility Criteria** | **Exclusion Criteria** | **Number Screened/ Eligible/ Enrolled/ Analyzed** | **AgeSexRace** | **Ulcer Type/ Severity at Baseline (Intervention Onset)** | **Treatment A**  | **Treatment B** | **Treatment C** | **Duration of Followup** | **Study Setting** |
| Houston, 200141USFair | Observational | Older population | Older; institutionalized; under current PU treatment | NR | NR/NR/70/68 | Age (Mean): NRFemale: NRRace: NR | Treatment A84% stage II16% stage III-IVTreatment B91% stage II9% 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, 200942JapanFair | Observational: retrospective | Malignant neoplasmCerebral diseaseOrthopedic diseaseCardiovascular diseaseGastrointestinal diseaseRenal 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 yearsFemale: NRRace: NR | Treatment A:38% stage I 62% stage IITreatment 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, yearCountryOverall 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, 200738USPoor | NR | Mean improvement of 0.82 cc reduction of wound volume per day | NR | NR | NR | NR | NR | NR |
| Breslow, 199339USFair | NR | Treatment A-2.1 cm2change from baseline to final 15% improvementTreatment B-4.2cm2 change from baseline to final (p<0.02)15% improvement | Treatment APU decreased by 2.1cm2 in 8 weeksTreatment BPU decreased by 4.2 cm2 in 8 weeks | NR | NR | NR | NR | NR |
| Brewer, 201040AustraliaFair | Treatment A: 100% (n=30)Treatment B: 100% (n=26) | NR | Treatment A: 11 weeks, mean healing time Treatment B: 21 weeks mean healing timep=0.006 | NR | NR | NR | NR | NR |
| Houston, 200141USFair | 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, 200942JapanFair | 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, yearCountryOverall 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, 200738USPoor | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Breslow, 199339USFair | 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, 201040AustraliaFair | NR | NR | NR | NR | NR | NR | NR | NR | The Eirene Lucas Foundation |
| Houston, 200141USFair | 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, 200942JapanFair | NR | NR | NR | NR | NR | NR | NR | NR | NR |