

ANTICANCER ENTERAL FEEDING COMPOSITION

This is a Continuation of application Ser. No. 08/066,138 filed 27 May 1993, now abandoned, which is a 371 of PCT/JP92/01264, Sep. 30, 1992.

TECHNICAL FIELD

The present invention relates to a novel anti-cancer enteral feeding composition and more particularly to an anticancer enteral feeding composition designed according to the concept of amino acid imbalance and provided in dosage forms suitable for oral or tube feeding, which composition is effective in treating patients with cancer and improving malnutrition in such patients.

BACKGROUND ART

Multiple amino acid preparations, when given to a patient with cancer, assist in upholding physical strength due to their alimentering effect but, at the same time, nourish cancer cells as well to encourage growth and proliferation of the cancer cells so that the best which can be expected with such preparations is a delayed loss of body weight. In other words, it is a fatal disadvantage of those preparations that they do not alleviate clinical symptoms or contribute to body weight gain.

In an attempt to overcome these disadvantages, the inventors of the present invention had developed a new amino acid infusion not including any sulfur-containing amino acids such as methionine in accordance with the concept of amino acid imbalance (Japanese Kokai Patent Publication No. 35049/1980). However, since an amino acid preparation as a cancer therapy is generally administered in a total parenteral nutrition (TPN) regimen, there is a constant risk of hospital infection. Moreover, because as a rule the preparation is repeatedly administered for about 2 consecutive weeks, the patient must tolerate the inconveniences of an indwelling catheter for administration which restricts movement seriously over that long period. Furthermore, the total parenteral nutrition (TPN) must be given in several repetitions with about one-month-long intervals and that exerts a considerable mental burden on the patient. In addition, TPN generally entails marked atrophy of the digestive tract mucosa and, in that sense, parenteral administration is a negative factor in the functional homeostasis of the alimentary canal. Therefore, for patients with cancer, the development of an enteral feeding preparation compatible with oral and tube feeding has been awaited in earnest. Incidentally, from solubility and stability considerations, there are certain limits to the composition of a preparation of that type and in view of the necessity to correct nutritional deprivation in cancer patients, there is a true need for an enteral feeding formulation which may contain many other nutrients inclusive of carbohydrates, fats, vitamins and minerals as well.

The object of the present invention is to provide a novel enteral feeding composition which can be orally ingested, in lieu of said parenteral amino acid infusion, to nourish cancer patients and inhibit growth of cancer cells and which can be provided in a stable dosage form even when protein, fat and carbohydrate are additionally incorporated therein.

The intensive research done to accomplish the above object led the inventors to the finding that a powder obtainable by emulsifying a fat together with amino acids and spray-drying the emulsion gives, on addition of water, a stable oil-in-water emulsion without giving rise to insoluble matter, that when the above powder is mixed with granulated

dextrin, there is obtained a feeding composition which can be very well dispersible in water, that the above composition is excellent in both nutritional competence and cancer cell growth inhibitory activity and that when used in conjunction with an anticancer drug, the composition synergistically potentiates its anticancer efficacy. The present invention has been conceived and developed on the basis of the above findings.

DISCLOSURE OF INVENTION

The invention is, therefore, directed to an anticancer enteral feeding composition characterized by comprising a powder obtainable by emulsifying a fat in an aqueous solution of protein source amino acids of the composition shown below in free amino acid equivalents and freeze-drying the resulting oil-in-water emulsion and in combination therewith granulated dextrin.

L-Amino Acid	(g/100 g)
Isoleucine	2.58-10.30
Leucine	4.21-16.82
Lysine	3.26-13.06
Phenylalanine	2.84-8.51
Threonine	1.89-5.67
Tryptophan	0.72-2.15
Valine	2.58-10.30
Histidine	1.46-4.38
Arginine	4.12-16.48
Alanine	2.15-8.58
Aspartic acid and/or asparagine	6.18-24.72
Glutamic acid and/or glutamine	10.31-41.22
Glycine	2.15-8.58
Proline	2.92-11.68
Serine	2.66-10.64
Tyrosine	0-3.0

Preferably, the anticancer enteral feeding composition of the present invention contains the following amino acids in the indicated proportions.

L-Amino acid (g/100 g)	Preferred range	Optimal range
Isoleucine	2.58-7.73	3.86-6.44
Leucine	4.21-12.62	6.31-10.51
Lysine	3.26-9.80	4.90-8.16
Phenylalanine	2.84-8.51	4.25-7.09
Threonine	1.89-5.67	2.84-4.33
Tryptophan	0.72-2.15	1.07-1.79
Valine	2.58-7.73	3.86-6.44
Histidine	1.46-4.38	2.19-3.65
Arginine	4.12-12.36	6.18-10.30
Alanine	2.15-6.44	3.22-5.36
Aspartic acid and/or asparagine	6.18-18.54	9.27-15.45
Glutamic acid and/or glutamine	10.31-30.92	15.46-25.76
Glycine	2.15-6.44	3.22-5.36
Proline	2.92-8.76	4.38-7.30
Serine	2.66-7.98	3.99-6.65
Tyrosine	0-2.0	0-1.0

The above amino acid formula has been selected with the following fact taken into consideration. Thus, anticancer drugs in general are known to impair the alimentary tract mucosa of cancer patients (Journal of Parenteral and Enteral Nutrition, Vol. 14, No. 4, Supplement 100S-105S, for instance). Therefore, any enteral feeding formula for cancer therapy preferably contains glutamine, an amino acid having gastrointestinal mucosal protecting activity, in an appropriate proportion. The above formula takes that fact into consideration.