beneficially address and alleviate adverse outcomes associated with low folate in cerebrospinal fluid. The present invention also addresses those who must take anti-thyroid drugs or thyroid stimulating drugs or hormones. Supplementation with folates and vitamin B12 along with either anti-thyroid drugs or thyroid stimulating drugs can provide a better means of preventing and/or treating folate deficiencies and the associated problems from such deficiencies.

This invention will help prevent and further help diagnose the cause of folate deficiencies in some individuals, as thyroid-related medical conditions are presently not part of the focus of the medical and pharmaceutical communities. Further, leading researchers in the field of cerebrospinal folate deficiency have mainly focused on antibodies attacking the folate receptor or mitochondrial defects as the cause of cerebrospinal folate deficiency.

There is clearly a need to make the relationship between thyroid function and folate deficiencies in cerebrospinal fluid known so that it may be prevented and treated. This invention addresses that need.

Summary

The present invention provides methods and compositions for preventing and/or treating people with thyroid-related medical conditions from developing problems associated with folate deficiencies. In one aspect, the present disclosure refers to a composition, comprising: (a) a drug, agent, or medication that acts as a replacement for a hormone that is normally produced by the thyroid gland selected from the group consisting of levothyroxine, levothyroxine sodium, liothyronine sodium, liotrix, thyroxine and triiodothyronine, and (b) a reduced folate selected from the group consisting of 5-methyltetrahydrofolic acid and 6(S)-5-methyltetrahydrofolate.

In some examples, the present disclosure provides a method of administering folate to people with thyroid-related medical conditions. In some examples, the present disclosure provides a method of administering folate and vitamin B12 to people with thyroid-related medical conditions. In some examples, the present disclosure further provides a method of administering a reduced folate to people with thyroid-related medical conditions. In some examples, the present disclosure further provides a method of

administering a reduced folate and vitamin B12 to people with thyroid-related medical conditions. Yet in another example, the present disclosure further provides a method of administering folinic acid and vitamin B12 to people with thyroid-related medical conditions. And in some examples the administration of folate and vitamin B12 will treat or prevent cerebrospinal folate deficiency, masked megaloblastic anemia, other macrocytic anemias (which include anemias that may be masked macrocytic anemias), or hepatic dysfunction . In some examples, the present disclosure will include the administration of folate and vitamin B12 and will be coupled with the administration of iron. Other examples will include the administration of L-carnitine and/or calcium and/or vitamin D along with the administration of folate and vitamin B12. With respect to calcium and vitamin D, these are preferred examples that also address parathyroid hormone deficiencies.

In some examples, the present disclosure provides a method of administering folate and vitamin B12 to people with hypothyroidism or hyperthyroidism. In other examples, the present disclosure provides a method of administering folate and vitamin B12 to people that have been treated with radioactive iodine, or who have had surgery on or related to their thyroid, or who have had any procedure that has reduced the size or activity of their thyroid gland. In another example, the present disclosure provides a method of administering folate and vitamin B12 to an individual having hypothyroxinemia or another temporary period of hypothyroidism. In yet another example, the present disclosure provides a method of administering folate and vitamin B12 to an individual that is a fetus or nursing child of a mother or caregiver who has a thyroid-related medical condition.

In some examples, the present disclosure provides a composition of a thyroid stimulating drug, a folate, and vitamin B12.

This example will facilitate prevention and treatment of folate deficiencies for persons that have hypothyroidism. In other examples, the composition will additionally include iron, and/or L-carnitine, and/or calcium, and/or vitamin D. In another example, the present disclosure provides a composition of an anti-thyroid drug, a folate, and vitamin B12. This example will facilitate prevention and treatment of folate deficiencies for persons that are being treated for hyperthyroidism and may also be complemented by iron, and/or L-carnitine, and/or calcium, and/or vitamin D.

In a preferred example of the disclosure, the methods and compositions for prevention and treatment of thyroid-related medical conditions will require 5-methyltetrahydrofolic acid, or another reduced folate, and vitamin B12. In another preferred example of the disclosure, the composition for prevention and treatment of thyroid related medical conditions will require 5-methyltetrahydrofolic acid, or another reduced folate, and vitamin B12 with either an anti-thyroid drug or a thyroid stimulating drug. In another preferred example, the composition of anti-thyroid drug or thyroid stimulating drug, folate or another reduced folate, and vitamin B12 will also comprise iron, and/or L-carnitine, and/or calcium, and/or vitamin D. With respect to calcium and vitamin D, these are the preferred examples that also address parathyroid hormone deficiencies.

Detailed Description of the Invention

I. Definitions

As used herein, "folate(s)" are a group of pteroyglutamate acids that become structurally and functionally altered when reduced. The term "folate" refers to folic acid and any derivatives thereof.

Folic acid, (N-[4-(2-Amino-3,4-dihydro-4-oxo-6-pteridmylmethylamino)-benzoyl]-L-glutamic acid) also known as

CLAIMS

1. A composition, comprising: (a) a drug, agent, or medication that acts as a replacement for a hormone that is normally produced by the thyroid gland selected from the group consisting of levothyroxine, levothyroxine sodium, liothyronine sodium, liotrix, thyroxine and triiodothyronine, and (b) a reduced folate selected from the group consisting of 5-methyltetrahydrofolic acid and 6(S)-5-methyltetrahydrofolate.

2. The composition of claim 1, wherein the reduced folate itself does not contain calcium.

3. The composition of claim 1, wherein the reduced folate is 5-methyltetrahydrofolic acid and the 5-methyltetrahydrofolic acid itself does not contain calcium.

4. The composition of claim 1, wherein the reduced folate is 6(S)-5-methyltetrahydrofolate and the 6(S)-5-methyltetrahydrofolate itself does not contain calcium.