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(54) **OPTIMIZING MIFEPRISTONE LEVELS FOR CUSHING'S PATIENTS**

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See application file for complete search history.

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(57) **ABSTRACT**

The present invention provides a method for optimizing levels of mifepristone in a patient suffering from Cushing's syndrome. The method comprises the steps of treating the patient with seven or more daily doses of mifepristone over a period of seven or more days; testing the serum levels of the patient to determine whether the blood levels of mifepristone are greater than 1631 ng/mL; and adjusting the daily dose of the patient to achieve mifepristone blood levels greater than 1631 ng/mL.

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OPTIMIZING MIFEPRISTONE LEVELS FOR CUSHING'S PATIENTS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application No. 62/150,757, filed Apr. 21, 2015, which is incorporated in its entirety herein for all purposes.

BACKGROUND OF THE INVENTION

It has been reported previously that administration of the same dose of mifepristone can produce widely varying blood serum levels in different patients. The varied blood serum levels can result in some patients not receiving an efficacious dose of mifepristone. For patients suffering from a mental disorder, the blood serum levels need to be maintained at about 1300 ng/mL. For patients suffering from Cushing's syndrome, it was surprisingly discovered that blood serum levels need to be maintained at a level of at least about 1631 ng/mL for a therapeutic response. Thus, a method for ensuring that the blood serum levels of mifepristone remain in an efficacious and safe range is needed for patients suffering from Cushing's syndrome.

BRIEF SUMMARY OF THE INVENTION

In one embodiment, the present invention provides a method for improving efficacy of mifepristone treatment in a patient suffering from Cushing's syndrome. The method includes treating the patient with seven or more daily doses of mifepristone over a period of seven or more days; testing the serum levels of the patient to determine whether the blood levels of mifepristone are greater than 1631 ng/mL; and adjusting the daily dose of the patient to achieve mifepristone blood levels greater than 1631 ng/mL. The patient of the present invention is not already suffering from a condition indicated for treatment with mifepristone. Thus, the method thereby improves the efficacy of mifepristone treatment for patients suffering from Cushing's syndrome for the patient suffering from Cushing's syndrome.

DETAILED DESCRIPTION OF THE INVENTION

I. Introduction

Administration of the same dose of mifepristone can produce widely varying mifepristone blood serum levels in different patients. For the same dose, the blood serum levels can differ by as much as 800% from one patient to another. For those patients with lower blood serum levels, the effectiveness of mifepristone treatment can suffer significantly. The present invention provides a method for optimizing the blood serum levels of mifepristone so that the blood serum levels remain in an efficacious range and the patient receives the necessary treatment.

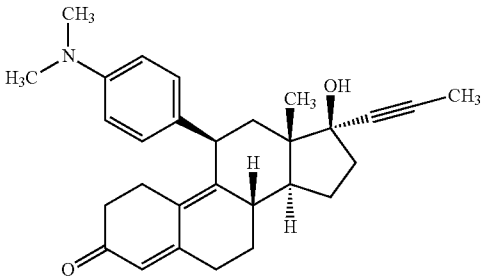
The method of the present invention optimizes blood serum levels of mifepristone in a patient suffering from Cushing's syndrome by first treating the patient with mifepristone. The treatment can be for any appropriate period of time, such as seven or more daily doses over a period of seven or more days. Following treatment for an appropriate

greater than 1631 ng/mL. The daily dose of the patient is then adjusted in order to achieve mifepristone blood levels of greater than 1631 ng/mL.

Previous methods of optimizing mifepristone levels are known for patients suffering from mental disorders. But the earlier methods describe a minimum mifepristone blood level of only 1300 ng/mL. While patients with Cushing's syndrome are known to have higher cortisol levels, it is surprising that higher mifepristone blood level of 1631 ng/mL would be necessary to achieve optimal efficacy in treating Cushing's syndrome.

II. Definitions

"Mifepristone" refers to a compound having the following structure:



The term mifepristone also refers to a family of compositions also known as: RU486 or RU38.486; 17-beta-hydroxy-11-beta-(4-dimethyl-aminophenyl)-17-alpha-(1-propynyl)-estra-4,9-dien-3-one); 11-beta-(4dimethylaminophenyl)-17-beta-hydroxy-17-alpha-(1-propynyl)-estra-4,9-dien-3-one); 11B[p-(Dimethylamino) phenyl]-17B-hydroxy-17-(1-propynyl)-estra-4,9-dien-3-one; 11B-(4-dimethyl-aminophenyl)-17B-hydroxy-17A-(prop-1-ynyl)-estra-4,9-dien-3-one; 17B-hydroxy-11B-(4-dimethylaminophenyl-1)-17A-(propynyl-1)-estra-4,9-diene-3-one; 17B-hydroxy-11B-(4-dimethylaminophenyl-1)-17A-(propynyl-1)-E; (11B,17B)-11-[4-dimethylamino)-phenyl]-17-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one; and 11B-[4-(N,N-dimethylamino) phenyl]-17A-(prop-1-ynyl)-D-4,9-estradiene-17B-ol-3-one. Salts, hydrates and prodrug forms of mifepristone are also useful in the formulations of the present invention.

Mifepristone and its analogs bind to the glucocorticoid receptor (GR), typically with high affinity, and inhibit the biological effects initiated/mediated by the binding of any cortisol or cortisol analogue to the GR. As such, mifepristone has been used to treat conditions associated with elevated cortisol levels including, for example, hyperadrenocorticism, also known as Cushing's syndrome (Chrousos, pp 273-284, In: Baulieu, ed. *The Antiprogestin Steroid RU 486 and Human Fertility Control*. Plenum Press, New York (1989), Sartor (1996) *Clin. Obstetrics and Gynecol.* 39:506-510). Patients with some forms of psychiatric illnesses can be responsive to treatments which block the effect of cortisol, as by administering GR antagonists (Van Look (1995) *Human Reproduction Update* 1:19-34). In one study, a patient with depression associated with Cushing's Syndrome was responsive to a high dose, up to 1400 mg per day, of mifepristone (Nieman (1985) *J. Clin Endocrinol. Metab.* 61:536). Due to its antiprogestogenic activity, mifepristone has also been employed in emergency contraception, medi-

"Patient" refers to animals such as mammals, including, but not limited to, primates (e.g., humans), cows, sheep, goats, horses, dogs, cats, rabbits, rats, mice and the like. The patient can have a condition known to be treated by glucocorticoid antagonists such as mifepristone. Such conditions include, but are not limited to, psychiatric illnesses and hormonal disorders. In certain embodiments, the patient is a human. The patient can be male or female.

"Cushing's syndrome" refers to an endocrine disease with an estimated incidence of approximately 10-15 per 1 million persons (Meier and Biller (1997) *Endocrinol Metab Clin North Am* 26:741-762), and is associated with an increased blood concentration of cortisol (hypercortisolism) over a long period of time. Cushing's syndrome is classified as either ACTH dependent or non ACTH dependent. ACTH dependent Cushing's syndrome is characterized by a chronic ACTH hypersecretion which stimulates the growth of the adrenal glands and the hypersecretion of corticosteroids. The most common underlying cause of ACTH dependent Cushing's syndrome is excessive production of ACTH by pituitary adenomas known as Cushing's disease. Cushing's syndrome resulting from the production of ACTH in another location than the pituitary gland is known as ectopic Cushing's syndrome. Examples of ectopic sites include thymoma, medullary carcinoma of the thyroid, pheochromocytoma, islet cell tumors of the pancreas and small cell carcinoma of the lung. ACTH independent Cushing's syndromes are caused by adrenal tumors that can be either adenomas or carcinomas. Both adrenal adenomas and carcinomas are characterized by chronic cortisol hypersecretion.

"Optimizing" refers to the process of testing mifepristone blood levels and adjusting the dosage of mifepristone administered to the patient in need in order to achieve mifepristone blood levels above 1631 ng/mL.

"Treat", "treating" and "treatment" collectively refer to any indicia of success in the treatment or amelioration of an injury, pathology or condition, including any objective or subjective parameter such as abatement; remission; diminishing of symptoms or making the injury, pathology or condition more tolerable to the patient; slowing in the rate of degeneration or decline; making the final point of degeneration less debilitating; improving a patient's physical or mental well-being; or, in some situations, preventing the onset of dementia. The treatment or amelioration of symptoms can be based on objective or subjective parameters; including the results of a physical examination, neuropsychiatric exams, and/or a psychiatric evaluation.

"Testing" refers to determining the mifepristone blood levels in a patient. The testing can be performed by any suitable instrument, such as a plasma sampling collection device capable of detecting mifepristone serum levels.

A patient "not already suffering from a condition indicated for treatment with mifepristone" is a patient who is not suffering from a condition which is known in the art to be effectively treatable with mifepristone. Conditions known in the art to be effectively treatable with mifepristone include drug withdrawal, psychosis, dementia, stress disorders, and psychotic major depression.

III. Method Of Optimizing Mifepristone Levels

The present invention provides a method of optimizing mifepristone levels in patients with Cushing's syndrome such that the blood serum levels remain at efficacious levels. The method involves administering mifepristone for a week, testing the blood serum levels of the Cushing's patient, and

The present invention provides a method for improving efficacy of mifepristone treatment in a patient suffering from Cushing's syndrome. The method includes treating the patient with seven or more daily doses of mifepristone over a period of seven or more days; testing the serum levels of the patient to determine whether the blood levels of mifepristone are greater than 1631 ng/mL; and adjusting the daily dose of the patient to achieve mifepristone blood levels greater than 1631 ng/mL. The patient treated in this method is not already suffering from a condition indicated for treatment with mifepristone, thereby improving the efficacy of mifepristone treatment for the patient suffering from Cushing's syndrome.

The seven or more daily doses of mifepristone can each be administered by any means suitable, as described in more detail below. In some embodiments, each of the seven or more daily doses of mifepristone are administered orally.

The seven or more daily doses of mifepristone can each be administered in any suitable dose. For example, the mifepristone can be administered in an amount of at least about 100 mg. The mifepristone can also be administered in an amount of about 300, 600, 900 or about 1200 mg. In some embodiments, the daily dose can be at least 300 mg. In some embodiments, the daily dose can be at least 600 mg. In some embodiments, the daily dose can be at least 900 mg. In some embodiments, the daily dose can be at least 1200 mg. Other daily doses are useful in the method of the present invention.

The daily doses can be administered for any suitable period of time that is at least 7 days in length. For example, the daily doses can be for 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, or 28 days. The mifepristone can be administered for longer periods as required by the patient being treated. In some embodiments, the patient can be treated with 28 or more daily doses over a period of 28 or more days.

The mifepristone blood levels can be tested by any means known to one of skill in the art. For example, the the testing can be performed by a plasma sampling collection device suitable for detecting mifepristone serum levels.

The mifepristone blood levels can be at any suitable level to treat Cushing's syndrome. For example, the mifepristone blood levels can be greater than about 1400 ng/mL, 1450, 1500, 1550, 1600, 1650, 1700, 1750, 1800, 1850, 1900, 2100, 2200, 2300, 2400, 2500, 2600, 2700, 2800 or great than about 2900 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1450 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1469 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1600 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1631 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1662 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1666 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1700 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1800 ng/mL. In some embodiments, the mifepristone blood level can be greater than 1820 ng/mL. In some embodiments, the mifepristone blood level can be greater than 2000 ng/mL. In some embodiments, the mifepristone blood level can be greater than 2022 ng/mL.

The daily dose can be adjusted to any suitable dose to maintain the mifepristone blood level above the necessary level. For example, if the mifepristone blood level is below 1631 ng/mL, the daily dose can be increased to 600 mg from

1200 mg from 300 mg. If after another seven daily doses, the mifepristone blood level is still not above the necessary level, the mifepristone daily can again be increased. For example, the mifepristone daily dose can be increased to 900 mg from 600 mg, to 1200 mg from 900 mg, or to 1200 mg from 600 mg. In some embodiments, the adjusting step comprises increasing the daily dose of the patient to achieve mifepristone blood levels greater than 1631 ng/mL. Additional adjustments in the daily doses can be made to maintain the mifepristone blood level above 1631 ng/mL.

Any suitable percentage of the patient population can have the optimal response to administration of the mifepristone. For example, at least 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100% of the patient population can achieve the optimal response to the mifepristone treatment. In some embodiments, at least about 20% of the patient population can have the optimal response to administration of the mifepristone. In some embodiments, at least about 40% of the patient population can have the optimal response to administration of the mifepristone. In some embodiments, at least about 60% of the patient population can have the optimal response to administration of the mifepristone.

A. Patients in Need

Patients amenable to treatment with mifepristone according to the method of the present invention suffer from Cushing's syndrome. Cushing's syndrome is a disorder resulting from increased adrenocortical secretion of corticosteroid. Hyperfunction of the adrenal cortex may be adrenocorticotropic hormone (ACTH)-dependent or it may be independent of ACTH regulation, e.g. production of corticosteroid by an adrenocortical adenoma or carcinoma. A common cause of Cushing's syndrome is excessive production of ACTH by the pituitary gland. This elevated level of ACTH in the bloodstream typically is produced by a pituitary adenoma (Cushing's disease), but in rare instances has a different etiology. Cushing's syndrome resulting from the production of ACTH in a location other than the pituitary gland is known as ectopic Cushing's syndrome. Examples of ectopic sites include thymoma, medullary carcinoma of the thyroid, pheochromocytoma, islet cell tumors of the pancreas and oat cell carcinoma of the lung. The overwhelming majority of Cushing's syndrome cases in humans, however, trace their etiology to a pituitary adenoma. Symptoms of Cushing's syndrome include weight gain, central obesity, steroid hypersecretion, elevated urinary cortisol excretion, moon face, weakness, fatigue, backache, headache, impotence, mental status changes, muscle atrophy, and increased thirst and urination compared to mammals not suffering from this disease. Diagnosis and treatment of Cushing's syndrome remains a challenge (see Oldfield, E. W. et al., N. Engl. J. Med., 325:897-905 (1991); Findling, J. W. et al., "Diagnosis and differential diagnosis of Cushing's syndrome," Endocrinol. Metab. Clin. North Am., 30:729-47 (2001); Orth, D. N., "Cushing's syndrome," N Engl J. Med., 332:791-803 (1995)). In experienced specialized centers, surgical resection of ACTH-secreting pituitary microadenomas offers an overall cure rate of about 70-80%, but for macroadenomas cure rates only approximate 30%, and the extensive surgical resection required portends significant risk to surrounding normal pituitary tissue, leading to partial or total hypopituitarism in about 80% of cases (Simmons, N. E. et al., "Serum Cortisol response to transphenoidal surgery for Cushing disease," J. Neurosurg., 95:1-8 (2001); Mampalam, T. J. et al., "Transsphenoidal microsurgery for Cushing's disease: a 216-[illegible]

resection in Cushing's disease: undetectable serum cortisol as the definition of successful treatment," Clin. Endocrinol., 38:73-8 (1993)).

B. Formulations of Mifepristone

Formulations of the present invention include mifepristone in combination with pharmaceutical excipients. Mifepristone is commercially available from a variety of sources such as Eurolabs Ltd. (London, England). Mifepristone can also be synthesized by one of skill in the art using known synthetic procedures.

Mifepristone refers to a family of compositions also referred to as RU486, or RU38.486, or 17-beta-hydroxy-11-beta-(4-dimethyl-aminophenyl)-17-alpha-(1-propynyl)-estra-4,9-dien-3-one), or 11-beta-(4dimethylaminophenyl)-17-beta-hydroxy-17-alpha-(1-propynyl)-estra-4,9-dien-3-one), or analogs thereof, which bind to the GR, typically with high affinity, and inhibit the biological effects initiated/mediated by the binding of any cortisol or cortisol analogue to a GR receptor. Chemical names for RU-486 vary; for example, RU486 has also been termed: 11B[p-(Dimethyl-amino)phenyl]-17B-hydroxy-17-(1-propynyl)-estra-4,9-dien-3-one; 11B-(4-dimethyl-aminophenyl)-17B-hydroxy-17A-(prop-1-ynyl)-estra-4,9-dien-3-one; 17B-hydroxy-11B-(4-dimethylaminophenyl-1)-17A-(propynyl-1)-estra-4,9-diene-3-one; 17B-hydroxy-11B-(4-dimethylaminophenyl-1)-17A-(propynyl-1)-E; (11B,17B)-11-[4-dimethylamino)-phenyl]-17-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one; and 11B-[4-(N,N-dimethylamino) phenyl]-17A-(prop-1-ynyl)-D-4,9-estradiene-17B-ol-3-one. Salts, hydrates and prodrug forms of mifepristone are also useful in the formulations of the present invention.

Formulations suitable for oral administration can consist of (a) liquid solutions, such as an effective amount of mifepristone suspended in diluents, such as water, saline or PEG 400; (b) capsules, sachets or tablets, each containing a predetermined amount of the active ingredient, as liquids, solids, granules or gelatin; (c) suspensions in an appropriate liquid; and (d) suitable emulsions. Tablet forms can include one or more of lactose, sucrose, mannitol, sorbitol, calcium phosphates, corn starch, potato starch, microcrystalline cellulose, gelatin, colloidal silicon dioxide, talc, magnesium stearate, stearic acid, and other excipients, colorants, fillers, binders, diluents, buffering agents, moistening agents, preservatives, flavoring agents, dyes, disintegrating agents, and pharmaceutically compatible carriers. Lozenge forms can comprise the active ingredient in a flavor, e.g., sucrose, as well as pastilles comprising the active ingredient in an inert base, such as gelatin and glycerin or sucrose and acacia emulsions, gels, and the like containing, in addition to the active ingredient, carriers known in the art.

The pharmaceutical preparation is preferably in unit dosage form. In such form the preparation is subdivided into unit doses containing appropriate quantities of the active component. The unit dosage form can be a packaged preparation, the package containing discrete quantities of preparation, such as packeted tablets, capsules, and powders in vials or ampoules. Also, the unit dosage form can be a capsule, tablet, cachet, or lozenge itself, or it can be the appropriate number of any of these in packaged form. The composition can, if desired, also contain other compatible therapeutic agents. Preferred pharmaceutical preparations can deliver the compounds of the invention in a sustained release formulation.

C. Administration of Mifepristone

The formulations of the present invention provide serum [illegible]

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