New drug may provide asthma relief

By Katherine Webster
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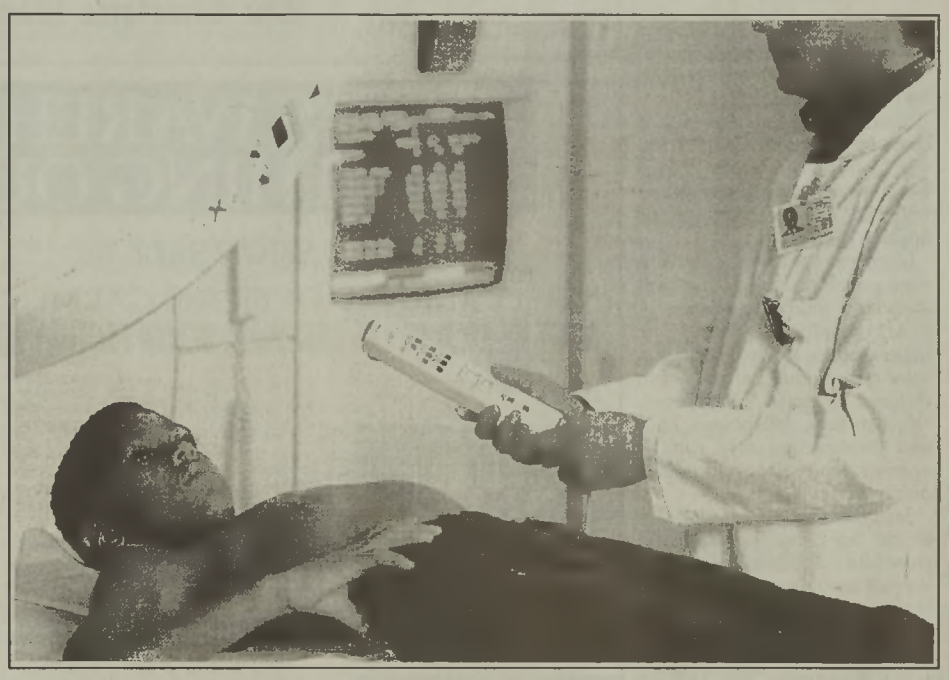

NEW YORK – Modest doses of inhaled steroids combined with other drugs control asthma as well as or better than high doses of steroids, while reducing the risk of side effects from long-term use, two studies found.

Steroids reduce the frequency of asthma attacks. But daily use over a few years has been linked to osteoporosis and cataracts in older adults and slowed growth in children. And the effects over decades of use are unknown because the drugs are so new.

Two studies published in Thursday's New England Journal of Medicine looked at drug combinations that might allow asthma sufferers to get by with lower doses of steroids.

"Taking two medications in modest quantities seems to improve control of the disease while reducing the possible long-term side effects," said Dr. Gilbert D'Alonzo, a professor of medicine at Temple University in Philadelphia who was not involved in either study.

Asthma afflicts 14 million to 15 million Americans, causing thousands of emergency hospitalizations and killing more than 5,000 people a year.

Inhaled steroids – the first-line approach to treating moderate or severe asthma – reduce the chronic lung inflammation that makes it hard for patients to breathe.

One of the studies looked at formoterol, an inhaled airway-relaxing type of drug known as a long-acting beta-2-agonist, in combination with the inhaled steroid budesonide. The study, led by Dr. Romain Pauwels at University Hospital in Ghent, Belgium, involved 852 patients ages 17 to 70 at hospitals in Europe and Canada.

After a year of treatment, patients getting formoterol and low doses of budesonide had fewer symptoms, better lung function and more asthma attack-free days than those getting moderate doses of budesonide alone. However, the higher dose of budesonide was more effective at preventing the most severe asthma attacks.

The combination of formoterol and a moderate dose of budesonide proved to be the best treatment of all.

In the other study, researchers from the Imperial College School of Medicine in London compared patients treated with high doses of budesonide with those getting a moderate dose of budesonide plus theophylline pills. Theophylline is known as a bronchodilator; it relaxes the airways.

The combination treatment was just as effective as high-dose treatment with the inhaled steroid alone, and was considerably cheaper: $60 per month, compared with $100 for the high dose of budesonide or $155 for a combination of moderate-dose budesonide and a beta-2-agonist called salmeterol.

Formoterol is available in Europe but is still awaiting Food and Drug Administration approval in the United States. Salmeterol is the only long-acting beta-2-agonist approved by the FDA. It has shown similar results when used in combination with an inhaled steroid, D'Alonzo said.

There are two distinct types of beta-2-agonists: Short-acting beta-2-agonists, such as albuterol, are used for quick relief during an asthma attack. Long-acting beta-2-agonists are taken twice a day to prevent attacks but do not help during acute episodes because they are slow to take effect.

NIH: Rise in rate of strokes

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WASHINGTON – Americans whose blood pressure is too high but who have no other disease risk factors should try exercise and other lifestyle changes for a year before resorting to drug therapy, the government recommended Thursday.

The new advice comes as the National Institutes of Health uncovers early signs that awareness and treatment of hypertension may be dropping after 25 years of improvements.

Studies indicate that nearly half of hypertension patients go untreated and just 68 percent even know they have high blood pressure, numbers that have dropped slightly from 1991. Also troubling, the NIH said, is a small rise in the rate of strokes and a leveling off of deaths from heart disease.

In its new hypertension guidelines, the NIH's National Heart, Lung and Blood Institute recommends specific treatment approaches for patients depending on how good their overall health is.

Blood pressure of 140 over 90 is considered high.

Among the guidelines:

• People whose pressure is high, but not above 159 over 99, and who have no risk factors for heart disease or organ damage should try to lose at least 10 pounds, exercise regularly and reduce alcohol and salt consumption for a year before turning to medication. These patients once were told to try lifestyle changes for just three to six months before turning to medicine.

• If these patients smoke, have diabetes, are over 60 or have a family history of heart disease, they should try lifestyle changes for just six months.

• If these patients have cardiovascular disease or signs of organ damage, they should immediately be prescribed blood pressure medicine.

• People whose blood pressure is 160 over 100 or higher should take medication immediately, regardless of other risk factors.

MD claim bogus, FDA says

THE ASSOCIATED PRESS

MEMPHIS, Tenn. – A federal agency ordered a Memphis foundation to stop making unproven claims about the safety and effectiveness of experimental muscular dystrophy therapy.

The Food and Drug Administration criticized the Cell Therapy Research Foundation's use of patient testimonials and said misleading statements about the FDA's role in foundation research should be corrected.

"These statements give a false sense of assurance to the readers of these Web pages that the FDA endorses the product or clinical trials," wrote William Purvis, advertising and promotional labeling staff director for the FDA's Center for Biologics Evaluation and Research.

The Nov. 6 letter to Dr. Peter K. Law and the foundation said the Internet home page includes unproven claims that the experimental treatment strengthens muscles, improves muscle performance and corrects the underlying gene defect.

Law resigned as a University of Tennessee at Memphis professor and launched a foundation in 1991 to develop a muscular dystrophy treatment.

The treatment, known as myoblast transfer therapy, relies on billions of healthy immature muscle cells known as myoblasts.

These donor myoblasts are injected into the diseased muscles of muscular dystrophy patients. The hope is that the healthy muscles, grown from donor muscle, will fuse with and rescue the patients deteriorating muscles.

The foundation is studying the therapy as possible treatment for Duchenne, Becker, and limb girdle muscular dystrophies. The FDA has okayed the research design and the foundation hopes to win FDA approval and expects to submit data for review next year.

At least 112 muscular dystrophy patients have participated in Law's research. Experimental treatment is not covered by health insurance, which means most families must raise $98,000 or more for their child to participate in foundation research.

Purvis warned the safety of the therapy has not been proven.

Law was traveling outside the United States Friday. Anthony Pietrangelo, the foundation's lawyer, said in a statement that foundation officials received the letter Nov. 7 and are committed to cooperating with the FDA.

Friday, the Web site included patient testimonials and language similar to that prompting the FDA complaint. But it also stated the foundation "makes no representations as to the (treatment) efficacy."

The foundation has 15 working days after receiving the letter to detail planned changes on its Internet site.

Federal regulations prohibit a researcher or company from promoting or making claims about experimental products or treatments.

Law has been criticized for not presenting experimental data more completely in scientific publications or at professional meetings.

Others say he is raising false hope among desperate families without evidence the treatment is safe and effective.

In July, Law filed an $11 million libel and slander suit against a handful of critics, including scientists in Pittsburgh, London and Sao Paulo, Brazil, the University of Pittsburgh, an Internet Web site administrator for both Pittsburgh and a nonprofit group raising money for muscular dystrophy research.

The suit is pending in federal court.