

## Research News

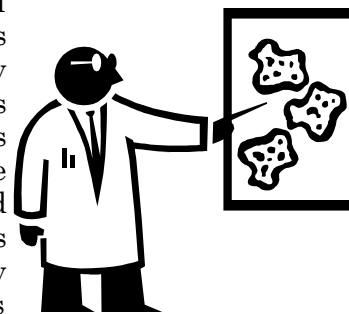
### Lauric Acid Clinical Trials For People Living With HIV/AIDS

Lauric.org is seeking a sponsor for a U.S. six month, three-site, proof-of-concept trial that they are developing based on newly designed lauric/capric acid protocols for HIV/AIDS (A-0114) and Mother-Infant HIV Transmission (A-0118).

In lipid coated virus (LCV) and lipid coated bacterium (LCB) research, a proof-of-concept clinical trial is an organized study conducted on people with specific LCVs such as HIV or LCBs such as listeria monocytogenes. The trial seeks to answer specific questions about new treatments and new ways of using treatments. The proof-of-concept clinical trial studies monoglycerides and may also look at them as adjunct to existing drugs already used for the treatment of LCVs and LCBs. The trial also looks at how changes in dietary intake of monoglycerides can help patients prevent LCVs and LCBs from occurring.

Lauric.org has a Proof-of-Concept Trial Preliminary Budget Cost Form on its web site for institutions to fill out if they are interested in participating and would like to be considered as a possible site. The proposed HIV/AIDS (A-0114) Proof-of-Concept Trial

will use pharmacologically naive participants and those individuals whom have failed treatment. The six-month study will test the use of lauric fats in the diet as physiologically functional foods to lower viral load and P24 antigen in HIV-infected individuals and to raise CD4 T-cells and/or CD4/CD8 T-cell ratios. The study will also determine subjective sense of well-being. Participants must be HIV-positive with an elevated viral load that is sufficiently elevated so that a measure of reduction could be determined. They must have a low CD4 T-cell count or a low CD4/CD8 value. HIV-positive individuals on many drugs including protease inhibitors



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and whose viral loads have been reduced to a level that is not measurable are excluded from the study. After the determination of laboratory values, participants will receive a supply of lauric fats previously determined to contain sufficient amounts of lauric and capric acid to provide 24-28 grams and 3-4 grams per person per day, respectively.

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For more information on the Proof-of-Concept Trial and lauric acid visit <<http://www.lauric.org/>>.

**Source:** HIV/AIDS Clinical Trials. Lauric.org Homepage. Bethesda, MD: Center For Research On Lauric Oils, Inc. WWW: <http://www.lauric.org/> (accessed 8 June 2001).

**“For more information on the Proof-of-Concept Trial and lauric acid visit <<http://www.lauric.org/>>.”**

### HAART And Anemia

Richard Semba and colleagues recently conducted a longitudinal study of HIV-infected intravenous drug users (IVDUs) in Baltimore, Maryland to examine the potential impact of highly active antiretroviral therapy (HAART) on anemia. Previous studies have shown that 15 to 30 percent of HIV-infected drug users may have anemia. A variety of etiologic factors are implicated in anemia including antiretroviral therapy, micronutrient deficiencies, anemia of chronic diseases, etc. Semba and colleagues thought that HAART might either worsen anemia, through increased bone marrow toxicity, or improve it through potential mechanisms, such as the improvement in micronutrient status or reduction of opportunistic infections (OIs) and associated anemia of chronic disease.

Investigators enrolled 102 subjects who received HAART and 103 control subjects who did not receive antiretroviral medications. Participants had a CD4+ lymphocyte count of less

than 500 cells/l in 1996. Hemoglobin, measured at baseline and at two subsequent visits, was low in 40% of the participants at baseline.

Participants not receiving HAART had a mean decrease in hemoglobin of  $4.2 \pm 1.1$  g/L ( $p < .0003$ ) and an increase in HIV load. Of those participants on HAART, there was a mean increase in hemoglobin of  $3.6 \pm 1.7$  g/L ( $p = .04$ ) along with a decrease in plasma HIV load at the one-year follow-up visit. An improvement in anemia was evident even after adjusting for body mass index, OIs, and gender. Identified potential mechanisms that may be involved include a reduction in OIs and anemia of chronic disease and an improvement in nutritional status.

**Source:** Semba RD, Shah N, Vlahov D. Improvement of Anemia Among HIV-Infected Injection Drug Users Receiving Highly Active Antiretroviral Therapy. *Journal of Acquired Immune Deficiency Syndromes* 2001; 26(4):315-319.

### Completed Clinical Trials

Stern and colleagues in New York, NY recently completed a 30-month study that builds upon information presented in the Nov/Dec 1996 HIV ReSource Review. The investigators enrolled 146 HIV-positive people

with evidence of cognitive impairment and CD4+ counts below 300/microL. Using the American Academy of Neurology criteria for probable HIV-1-associated dementia complex (HIV-D), 45 participants subsequently met criteria for incident HIV-D. Identified early risk factors of HIV-D included cognitive deficits, minor cognitive/motor disorder, and depression. Request article reprints from Yaakov Stern, PhD, Sergievsky Center, 630 W 168th St, New York, NY 10032 (e-mail: [ys11@columbia.edu](mailto:ys11@columbia.edu)).

**Source:** Stern Y, McDermott MP, Albert S, Palumbo D, et al. Factors Associated With Incident Human Immunodeficiency Virus-Dementia. *Arch Neurol* 2001;58(3):473-9.

### Plants And Vaccines

While he was at Texas A&M University in the early 1990s, Charles Arntzen thought about the idea of genetically engineered food to produce vaccines in their edible parts <<http://www.sciam.com/2000/0900issue/0900langridge.html>>. Using plants to produce and deliver a vaccine could reduce both the manufacturing cost and the risk of contamination from animal or human tissue cultures <<http://www.reutershealth.com/archive/2001/05/22/eline/links/20010522elin035.html>>. Researchers are now studying bananas, potatoes, tomatoes, lettuce, corn, rice, wheat and

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soybeans as alternatives to injectable vaccines.

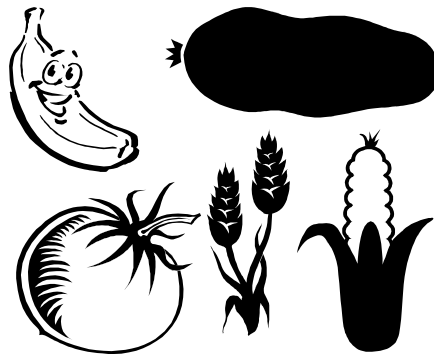
Animal studies and small human tests over the past ten years have encouraged edible vaccine studies. Food vaccines are engineered to hold antigens but not genes that would enable whole pathogens to form. Theoretically, since edible vaccines come into contact with the lining of the gastrointestinal tract they should activate mucosal and systemic immunity. This intrigues researchers who hope it will improve protection against microorganisms such as those that cause diarrhea. Along with other investigators Arntzen, who is now at Cornell University, demonstrated that both potato and tomato plants can synthesize antigens from the hepatitis B virus and other pathogens.

Researchers report that plants could deliver an HIV vaccine in the future. Investigators are currently working on packing HIV-suppressing proteins into spinach to make a more practical vaccine. The project is viewed as "the first step in the use of plants as a cheap, safe method of delivering AIDS vaccines" <[http://www.kaisernet.org/daily\\_reports/print\\_report.cfm?DR\\_ID=4768&dr\\_cat=1](http://www.kaisernet.org/daily_reports/print_report.cfm?DR_ID=4768&dr_cat=1)>. Dr. Alexander Karasev and colleagues at Thomas Jefferson University are focusing on developing a preventive vaccine for HIV. The vaccine would also help to treat people already

infected with the virus. Instead of eating the spinach people may be able to take special tablets if the tablets can be made as effective as the plant vaccine. Hopefully, the little funded effort to develop edible vaccines will continue and be successful.

### Sources:

- Langridge WHR. Edible Vaccines. Scientific American; Sept 2000. WWW: <http://www.sciam.com/2000/0900issue/0900langridge.html> (accessed 6 June 2001).
- Mundell EJ. Plants may someday deliver HIV vaccine. Reuters Health, 22 May 2001. WWW: <http://www.reutershealth.com/> (accessed 2 June 2001).
- Plants Could Deliver HIV Vaccine in the Future, Researchers Say. Kaiser Daily HIV/AIDS Report. 24 May 2001. WWW: <http://www.kaisernet.org/> (accessed 2 June 2001).



**Researchers are now studying bananas, potatoes, tomatoes, lettuce, corn, rice, wheat and soybeans as alternatives to injectable vaccines.**

HIV In Newly Infected People  
Information from the University Of North Carolina At Chapel Hill notes that in addition to high levels of HIV in the blood scientists have discovered high levels of HIV in the saliva, spinal fluid, semen and vaginal fluid of newly infected people. Although HIV levels were as high or higher than those in people with advanced HIV infection, newly infected patients had all been infected within the previous 90 days. Investigators noted that during the first weeks after contracting HIV many people have flu or mononucleosis-like symptoms including fever, muscle aches, rash, swollen glands and sore throat. Viral load dropped rapidly in all fluids after treating the patients with the latest drugs.

Pilcher, Assistant Professor of Medicine at the University of North Carolina at Chapel Hill, notes that combination anti-retroviral therapy "could become a public health strategy to reduce shedding of virus from semen and vaginal fluid", possibly reducing the number of new HIV infections. Since routine antibody tests to HIV may be negative in newly infected people, diagnosing very early infections with tests such as the polymerase chain reaction (PCR) could help to detect the presence of the virus.

**Source:** Williamson D. Scientists Find Heavy HIV Levels In Patient Fluids Less Than 30

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Days After Start Of Flu-Like Symptoms. University Of North Carolina News Services: Chapel Hill, NC; 17 May 2001. WWW: <http://www.unc.edu/news/newsserv/research/hiv052201.htm> (accessed 5 June 2001).

### Focus: Vitamins B12 And Folate

A recent Arbor Clinical Nutrition Update highlighted vitamins B12 and folate, which are found to be borderline deficient in elderly patients. Since the information looked at their relationship to cognitive dysfunction (covered in the Nov/Dec 1996 and Nov/Dec 1999 HIV ReSource Review issues) we thought this information might be useful.

The update notes a Swedish study of psychogeriatric patients, which correlated serum homocysteine levels with cognitive and psychosocial function. Italian researchers, however, did not find an independent relationship between B12 and folate status and cognitive functioning. Complimenting information presented in the Nov/Dec 1999 Review issue, English investigators report that vitamin B12 treatment can help improve higher brain function in patients with cognitive impairment but not in dementia patients.

For more information and references for these studies visit <http://arborcom.com>.

**Source:** Arbor Clinical Nutrition Update #89: B Vitamins And The Elderly Part I. Arbor Clinical Nutrition Updates <<http://arborcom.com>> 12 Apr 2001.

### Examining Sex Differences In HAART-Associated Dyslipidemia

Recent research sought to reveal potential sex differences in metabolic side effects of a newly initiated HAART therapy that included Nelfinavir, Didanosine, and Stavudine. The prospective longitudinal cohort study, which enrolled 40 HIV-positive people (27 males/13 females) and 35 healthy controls, took place at a Austria University Hospital. Patients had not taken any protease inhibitors before, were weight stable, and did not have any acute opportunistic infections.

Upon completion of the study, investigators learned that during HAART metabolic adverse effects are more pronounced in women. The women on HAART had higher triglycerides and leptin levels and their fasting insulin levels and LDL:HDL (low-density lipoprotein:high-density lipoprotein) ratio increased.

**Source:** Sex Differences In HAART-Associated Dyslipidaemia. Pernerstorfer-Schoen H, Jilmaa B, Perschler A, Wichlas S, et al. AIDS 2001;15(6):725-734. WWW:

<http://www.aidsonline.com> (accessed 6 June 2001).

### Hyperlactatemia In HIV-Infected Patients

Australian investigators recently sought to determine the prevalence, course and risk factors for hyperlactatemia in a prospective, longitudinal study of 349 HIV-positive patients. Participants were from the Western Australian HIV Cohort Study. Most patients on HAART experienced mild, chronic, asymptomatic hyperlactatemia. Two patients experienced severe fulminant lactic acidosis and hepatic steatosis that was attributed to nucleoside analogue reverse transcriptase inhibitors (NRTI). Five patients with lesser elevations of lactate, nausea or stomach discomfort and evidence of hepatic steatosis had their NRTI therapy revised and had relief of symptoms and a fall in lactate levels. The researchers found that treatment with Stavudine was the predominant risk factor for the development of chronic hyperlactatemia.

**Source:** Chronic Hyperlactatemia In HIV-Infected Patients Taking Antiretroviral Therapy. John M, Moore CB, James IR, Nolan D, et al. Perth, Western Australia. AIDS 2001;15(6):717-723.

### Women And Oral Mucosal Lesions

Greenspan and colleagues assessed the prevalence of oral lesions in a subset of women - 729 women (577 HIV-positive and 152 HIV-negative) - enrolled in the Women's Interagency HIV Study (WIHS). HIV-positive women had a higher occurrence of hairy

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leukoplakia, pseudomembranous candidiasis, erythematous candidiasis, and all oral candidiasis (pseudomembranous and/or erythematous). Although Kaposi's sarcoma was seen in 0.5% of HIV-positive women, it did not occur in HIV-negative women. For the HIV-positive women, oral candidiasis was associated with a CD4 T-cell count of less than 200 cells/l, cigarette smoking, and heroin or methadone use while hairy leukoplakia was associated with a high viral load.

**Source:** Greenspan D, Komaroff E, Redford M, Phelan JA, et al. Oral Mucosal Lesions and HIV Viral Load in the Women's Interagency HIV Study (WIHS). *J Acquir Immune Defic Syndr* 2000;25(1):44-50.

### Aphthous Stomatitis And Micronutrients

A recent study compared food intake among control patients and 118 patients with recurrent aphthous stomatitis (RAS group). Patients completed food frequency questionnaires that investigators used to determine food intake patterns. Final analysis of food intake patterns led the researchers to believe that iron, vitamin B1, calcium and vitamin C might be deficient in the RAS group. Although study participants were not identified as HIV-positive, this study is of interest to people who must deal with recurrent aphthous stomatitis.

**Source:** Ogura M, Yamamoto T, Morita M, Watanabe T. A Case-Control Study On Food Intake Of Patients With Recurrent Aphthous Stomatitis. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod*, 2001;91(1):45-9.

### Current Trials

To view information on clinical trials for Hepatitis B (HBV) and Hepatitis C (HCV) infection visit <http://www.hivandhepatitis.com>.

### Ongoing Clinical Trials

#### AIDS Wasting in Women And Testosterone

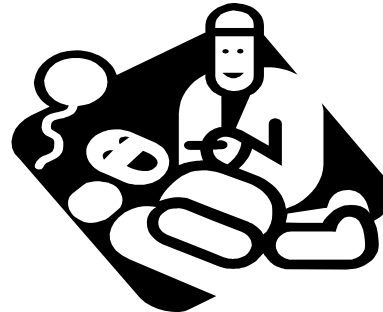
This is a one-year trial of women living in the New England area with HIV-related unintentional weight loss. Women wear either testosterone patches or placebo patches for the first six months. All women receive open-label testosterone patches for an additional six months. Patients receive up to \$650. **Inclusion Criteria:** HIV positive women between 18 and 45 years old with low blood testosterone and more than 10% unintentional weight loss or less than 90% of ideal body weight. Must be able to make monthly visits to Massachusetts General Hospital. **Exclusion Criteria:** Women who are pregnant or breastfeeding, have acute opportunistic infections or

use of androgens, estrogens or megestrol within three months of study entry.

### **Potential participants may**

**c o n t a c t :**

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**Although study participants were not identified as HIV-positive, this study is of interest to people who must deal with recurrent aphthous stomatitis.**

Massachusetts General Hospital is also conducting several lipodystrophy studies, both observational and treatment (metformin & rosiglitazone).

Read Leslie Hanna's view of clinical trials and HIV-positive women at <http://www.thebody.com/sfaf/winter01/women.html>.

### Health-Related Intervention (Unity Project)

The Unity Project provides one-on-one counseling and education intervention sessions to both men and women on a randomized basis for 30 months. Participants either begin sessions initially or wait two years before receiving sessions. They are compensated regardless of when they receive intervention sessions. The program addresses issues related to quality of life,

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sexuality, and health care.  
**Inclusion Criteria:** HIV positive people at least 18 years old who will remain in the San Francisco Bay Area for the study period.

### P o t e n t i a l participants may contact:

Neal Carnes <NCarnes@psg.ucsf.edu>, UCSF Center for AIDS Prevention Studies, 74 New Montgomery Street, Suite 600, San Francisco, CA 94105 (415) 597-4669. To view a complete list of the studies conducted through the Center For AIDS Prevention Studies visit <<http://www.caps.ucsf.edu/capsweb/projectregistry.html>>.

### The FRAME Study

This randomized six-month study aims to determine if metformin (Glucophage) plus nutritional counseling is effective in reducing abdominal fat in HIV-positive people. Patients are required to stay overnight on the Clinical Study Unit to have tests done. Tests include body mass composition, body urine collection and food diaries with a dietitian. Patients receive either metformin or placebo and nutritional counseling throughout the course of the study. They also receive transportation costs and are paid up to \$280 for completing the study. **Inclusion Criteria:**

**“Patients receive either metformin or placebo and nutritional counseling throughout the course of the study.”**

HIV-positive people at least 18 years old with increased abdominal girth since beginning protease inhibitors. Patients must be taking protease inhibitors or have discontinued them for at least three months with no decrease in abdominal girth. In addition, patients must have a waist/hip ratio of at least 0.95 in men or 0.85 in women. **Exclusion Criteria:** Diabetes, use of corticosteroids, anabolic steroids or growth hormone, significant heart, kidney or liver disease, pregnant or breastfeeding women, active alcohol abuse or acute infections within the past month.

### Potential participants may contact:

Kerry Coon <kerry.coon@tufts.edu>, Tufts University School of Medicine, 136 Harrison Avenue, Stearns 3, Boston, MA 02111 (617) 636-0810.

### The Nutrition for Healthy Living Study

This Boston study enrolls HIV-positive people and attempts to determine how nutrition affects HIV disease progression. It evaluates the long-term effects of the disease on nutritional status, metabolism, and body composition. Researchers also

hope to define the effects of HAART medication on nutritional status, metabolism, and body composition and assess nutritional and metabolic risk factors for heart disease and diabetes. Researchers also observe how nutrition affects quality of life, functional status, and physical performance. **Eligibility Criteria:** HIV-positive at least 18 years old who can attend two initial study visits one week apart and one 2 ½ hour visit every six months for three years. Participants must be available for telephone contact between visits. All participants receive nutritional counseling by a nutritionist who develops an eating plan tailored to meet individual health needs. Participants receive \$50 at each visit after the initial enrollment visit. **For more information call:** 617/636-3636.

To view a complete list of the studies conducted through the Tufts University School of Medicine in Boston, MA visit <[http://www.tufts.edu/med/nutrition\\_HIV/studies/Research.html](http://www.tufts.edu/med/nutrition_HIV/studies/Research.html)>.

Visit The Body to see what major clinical trials are going on throughout the US <[http://www.thebody.com/sfaf/winter01/clinical\\_trials.html](http://www.thebody.com/sfaf/winter01/clinical_trials.html)>.