Purpose

The purpose of this study is to determine the safety, tolerability, and preliminary efficacy of long-term use of high fat/high calorie and high calorie diets in people with amyotrophic lateral sclerosis (ALS) (Lou Gehrig's disease).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amyotrophic Lateral Sclerosis</td>
<td>Dietary Supplement: Oxepa&lt;br&gt;Dietary Supplement: Jevity 1.5&lt;br&gt;Dietary Supplement: Jevity 1.0</td>
<td>Phase II</td>
</tr>
</tbody>
</table>

Study Type: Interventional
Study Design: Allocation: Randomized<br>Control: Placebo Control<br>Endpoint Classification: Safety Study<br>Intervention Model: Parallel Assignment<br>Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)<br>Primary Purpose: Treatment

Official Title: Phase II Safety and Tolerability Study of High Fat/High Calorie Versus High Calorie Versus Optimal Nutrition in Subjects With Amyotrophic Lateral Sclerosis

Resource links provided by NLM:

Genetics Home Reference related topics: amyotrophic lateral sclerosis
Further study details as provided by Massachusetts General Hospital:

Primary Outcome Measures:
- Adverse events and subject compliance rates. [Time Frame: 5 months follow-up]  
  [Designated as safety issue: Yes]

Secondary Outcome Measures:
- Biomarkers of body composition and lipid metabolism [Time Frame: 5 months follow-up]  
  [Designated as safety issue: No]

Estimated Enrollment: 60
Study Start Date: October 2009
Estimated Study Completion Date: December 2011
Estimated Primary Completion Date: September 2011 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>High fat/high calorie</td>
<td>Dietary Supplement: Oxepa</td>
</tr>
<tr>
<td>Experimental High fat/high calorie diet: Oxepa</td>
<td>Oxepa: Tube feed containing 1.5 calories/ml of which 55% calories are from fat, including eicosapentaenoic acid and gamma-linolenic acid. Subjects will receive 1.25 times their daily caloric requirements based on their measured resting energy expenditure. Subjects will receive 4 months of tube feeds and be followed for an additional 1 month to measure adverse events and tolerability.</td>
</tr>
<tr>
<td>High calorie: Active Comparator</td>
<td>Dietary Supplement: Jevity 1.5</td>
</tr>
<tr>
<td>High calorie diet: Jevity 1.5</td>
<td>Jevity 1.5: Tube feed containing 1.5 calories/ml of which 29.4% are from fat. Subjects will receive 1.25 times their daily caloric requirements based on their measured resting energy expenditure. Subjects will receive 4 months of tube feeds and be followed for an additional 1 month to measure adverse events and tolerability.</td>
</tr>
<tr>
<td>Control: Placebo Comparator</td>
<td>Dietary Supplement: Jevity 1.0</td>
</tr>
<tr>
<td>Control diet: Jevity 1.0</td>
<td>Jevity 1.0: Control tube feed. Subjects will receive 1.0 times their daily caloric requirements based on their measured resting energy expenditure. Subjects will receive 4 months of tube feeds and be followed for an additional 1 month to measure adverse events and tolerability.</td>
</tr>
</tbody>
</table>

Detailed Description:

Weight loss is a common and severe symptom of amyotrophic lateral sclerosis (ALS), caused both from inadequate calorie intake and an increased metabolic rate. People with ALS are generally instructed to increase their calorie intake; however, the ideal amount and type of calories has not been studied. Several studies in an animal model of motor neuron disease have shown that a high fat/high calorie diet can increase survival by as much as 38%. Mice on a high
fat diet also live longer than mice fed diets consisting of high protein or high sugar. We are therefore conducting a phase II safety, tolerability, and preliminary efficacy trial in ALS of high fat versus high calorie versus normal diet. The normal diet will be calculated based on the number of calories needed to replace each participant's measured daily calorie requirement.

**Eligibility**

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:
1. Clinical diagnosis of ALS
2. Male or female subjects aged 18 years or older
3. Must already be tolerating tube feedings through either a gastrostomy tube (G-tube or PEG) or jejunostomy tube (J-tube)
4. Must require non-invasive ventilation (BIPAP) for less than 8 hours/day and have a Forced Vital Capacity (FVC) greater than 40% of predicted
5. Women of childbearing potential must have a negative pregnancy test at screening and be non-lactating.

Exclusion Criteria:
1. History of hepatitis including non-alcoholic steatohepatitis (NASH), cholecystectomy, prior biliary disease such as gallstones
2. History of diabetes
3. History of prior myocardial infarction or stroke
4. Laboratory values: Screening alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 2.0 times the upper limit of normal or total bilirubin greater than 1.5 times the upper limit of normal
5. Allergy to soy, fish, or milk products

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00983983

**Contacts**

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Sponsors and Collaborators

Massachusetts General Hospital
Muscular Dystrophy Association

Investigators

Principal Investigator: Anne-Marie A Wills, M.D.  
Massachusetts General Hospital

More Information

Additional Information:

Muscular Dystrophy Association (MDA) search engine for ongoing ALS clinical trials

Publications:


Responsible Party: Massachusetts General Hospital (Anne-Marie A. Wills, M.D. Instructor in Neurology)

ClinicalTrials.gov Identifier: NCT00983983

Other Study ID Numbers: MDA136152, 2009-P-001132

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Health Authority: United States: Institutional Review Board

Keywords provided by Massachusetts General Hospital:

**Amyotrophic Lateral Sclerosis**
- Adults with Amyotrophic Lateral Sclerosis (ALS)
- ALS
- Motor Neuron Disease
- MND
- Fat
- Lipid

**Cholesterol**
- Omega-3 fatty acid
- Diet
- Tube feed
- Gastrostomy
- PEG

Additional relevant MeSH terms:

**Amyotrophic Lateral Sclerosis**
- Nervous System Diseases
- Neurodegenerative Diseases
- Neuromuscular Diseases
- Pathologic Processes

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