Non-Invasive Measurement of Gastrointestinal (GI) Motility in Patients With Amyotrophic Lateral Sclerosis (ALS) (GIDysmotility)

This study is currently recruiting participants.
Verified by Drexel University, July 2008

First Received: July 10, 2008   Last Updated: April 6, 2009   History of Changes

Purpose

Recent evidence implicates abnormalities of autonomic function in ALS including problems with gastrointestinal (GI) motility. GI complaints reported by ALS patients such as constipation, diffuse abdominal pain, and a feeling of fullness or nausea may be attributed to autonomic involvement. Toepfer et al. found delayed gastric emptying in most ALS patients, indicating autonomic dysfunction (Gastrointestinal dysfunction in amyotrophic lateral sclerosis. Amyotrophic Lateral Sclerosis Other Motor Neuron Disord 1999; 1:15—19). The same authors also reported markedly prolonged colon transit time in ALS (Toepfer et al: Delayed colonic transit times in amyotrophic lateral sclerosis assessed with radio-opaque markers. Eur J Med Res 1997; 2:473—476).

The present study will investigate the GI transit time in a large cohort of patients and controls using a noninvasive technique that measure hydrogen gas production with the digestion of lactulose in a measured substrate load presented to the bowel.

Resource links provided by NLM:
clinicaltrials.gov/ct2/show/NCT00714805...
Further study details as provided by Drexel University:

Estimated Enrollment: 60
Study Start Date: January 2007
Estimated Study Completion Date: December 2009
Estimated Primary Completion Date: August 2009 (Final data collection date for primary outcome measure)

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<th>Groups/Cohorts</th>
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<td>ALS</td>
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<td>Subjects having either definite or probable ALS by El Escorial Criteria.</td>
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<tr>
<td>Healthy Control</td>
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<td>Subjects having no known ailment.</td>
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Detailed Description:

This study will examine how much time it takes for the food to travel along the intestines from mouth or stomach (if you have a feeding tube) to the end of the large intestine using a special instrument that measures hydrogen gas in your breath. Data collection will start after you sign this consent form. The only procedures that would be above and beyond routine care are indicated below:

In order to prepare for the study you will be asked to be off all medications that affects the GI motility for 24 hours. You will also be asked to fast overnight (starting midnight) the day before the test.

After fasting overnight, the test will be performed in the morning (at the Neurology Outpatient Clinic or at your home). Before eating or drinking anything a baseline measurement will be taken by breathing into the hydrogen meter. This will be just normal breathing. You will then drink a test meal consisting of 250 ml (approximately 1 cup) of a lactose (type of sugar) free supplement (For example Ensure) that has 20 grams of Lactulose added. If you have a peg tube then the supplement will be given through the tube. After 10 minutes you will again be asked to breath into the machine to measure the hydrogen gas levels. This will be repeated every 10 minutes until the hydrogen levels rise to a certain level or until 4 hours have passed.

Eligibility

Ages Eligible for Study: 18 Years to 89 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes
Sampling Method: Non-Probability Sample

Study Population

ALS clinic patients at MDA/ALS Center of Hope.

Criteria
Inclusion Criteria:

For the Disease Population:
- Diagnosis of definite or possible ALS by the El Escorial Criteria
- No previously known gastrointestinal problems
- Able to fast and hold medicines (anticholinergics and prokinetics) overnight prior to the measurement of GI motility
- No unstable medical problems and no evidence of dehydration by examination (skin turgor)

For Healthy Control
- No known gastrointestinal illness
- Able to fast and hold medicines (anticholinergics) overnight prior to the measurement of GI motility
- No unstable medical problems or evidence of dehydration

Exclusion Criteria:
- Patients or controls who are dehydrated
- Patients or controls who have evidence of previous gastrointestinal disease
- Patients with any unstable medical condition
- Patients unable to give informed consent
- Patients unable to blow into the breath analyzer and have steady breathing for one minute

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00714805

Locations

United States, Pennsylvania

MDA/ALS Center of Hope  Recruiting
Philadelphia, Pennsylvania, United States, 19104
Contact: Christine Barr, RN  215-762-5186  cbarr@drexelmed.edu
Principal Investigator: Terry Heiman-Patterson, MD

Sponsors and Collaborators

Drexel University College of Medicine
MDA/ALS Center of Hope

More Information

No publications provided

Responsible Party: MDA/ALS Center of Hope (Terry Heiman-Patterson, MD)
ClinicalTrials.gov Identifier: NCT00714805  History of Changes
Other Study ID Numbers: Internal-16637
Study First Received: July 10, 2008
Last Updated: April 6, 2009
Health Authority: United States: Institutional Review Board

Keywords provided by Drexel University:
Amyotrophic Lateral Sclerosis
Gastric Motility
Autonomic Nervous System
Neurodegenerative Diseases
Movement Disorders

Additional relevant MeSH terms:

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ClinicalTrials.gov processed this record on August 05, 2010