Molecular Imaging Modality by Positron Emission Tomography Using 18F-X: Study of Microglial Activation in Amyotrophic Lateral Sclerosis

**Purpose**

PET imaging of activated microglia offers a tool of investigation of a range of brain diseases where neuroinflammation is a component.

**Amyotrophic lateral sclerosis** is the most frequent motoneuronal disease in adult.

This study was designed to explore the feasibility of molecular imaging modality by Positron Emission Tomography using 18F-X as an in vivo marker of activated microglia for the assessment of neuroinflammation in amyotrophic lateral sclerosis.

PET may help in the diagnosis of the disease and, further, may allow assessment of the efficacy of antiinflammatory treatment.

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<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Amyotrophic Lateral Sclerosis Bulbar Disease</td>
<td>Radiation: 18F-X PET SCAN</td>
<td>Phase I</td>
</tr>
<tr>
<td>Spinal Disease</td>
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Study Type: Interventional

Study Design:
- Allocation: Non-Randomized
- Control: Active Control
- Endpoint Classification: Pharmacokinetics/Dynamics Study
- Intervention Model: Single Group Assignment
- Masking: Open Label
- Primary Purpose: Diagnostic

Official Title: Molecular Imaging Modality by Positron Emission Tomography Using 18F-X: Study of Microglial Activation in Amyotrophic Lateral Sclerosis
Further study details as provided by University Hospital, Tours:

Primary Outcome Measures:

- Quantitative in vivo-imaging of 18F-X microglial binding site as a measure of disease activity followed up by non-invasive quantification of patients using imaging modality.
  [ Time Frame: Inclusion period ]

Secondary Outcome Measures:

- Evidence of the localization of benzodiazepine binding site related to microglial activation in ALS
  [ Time Frame: inclusion period ]
- Evidence of the difference of microglial localization and activation between bulbar and spinal form of amyotrophic lateral sclerosis
  [ Time Frame: inclusion period ]

Estimated Enrollment: 30
Study Start Date: January 2007
Estimated Study Completion Date: December 2010

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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>1: Experimental 18F-X PET Scan imaging</td>
<td>Radiation: 18F-X PET SCAN 18F-X PET Scan: Injection of 7.8 mSv for 370 MBq of dose (0.021 mSv / MBq)</td>
</tr>
</tbody>
</table>

Detailed Description:

18F-X PET will be carried out requiring arterial sampling in 2 patients suffering from ALS and 2 normal subjects in order to evaluate the 18F-X quantification.

Then simplified PET using 18F-X will be carried out in 13 patients and 13 normal subjects.

Binding potential maps showing specific binding of 18F-X will be generated for each subject.

Regional binding potential values will be calculated for anatomically defined regions of interest after coregistration to and special transformation into the subject's own MRI.

Eligibility

Ages Eligible for Study: 40 Years to 70 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
suffering from probable or definite form of amyotrophic lateral sclerosis according to El Escorial criteria. Spinal or bulbar site of the disease.

- Information and signature of the written consent form
- French Social Security registration

Exclusion Criteria:

- Family history of ALS
- Riluzole treatment before the first PET scan.
- Psychiatric disorders
- Evolution of the disease older than 18 months
- Antiinflammatory or antibiotic treatment in the last month

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00563537

**Contacts**

Contact: Catherine ROUSSEL  (33) 2.47.47. 97.89  roussel@med.univ-tours.fr

**Locations**

France, Region Centre

Service de Médecine Nucléaire et Ultrasons - Hôpital Bretonneau  
Tours, Region Centre, France, 37044  
Sub-Investigator: Caroline PRUNIER, MD  
Sub-Investigator: Julien PRALINE, MD

**Sponsors and Collaborators**

University Hospital, Tours

**Investigators**

Study Director: Denis GUILLOTEAU, PHD  
Service de médecine nucléaire in Vitro - CHRU TOURS

Principal Investigator: Philippe CORCIA, MD  
Service de Neurologie - CHRU Tours

**More Information**

Publications:


Responsible Party: University Hospital, Tours
ClinicalTrials.gov Identifier: NCT00563537  History of Changes
Other Study ID Numbers: PHRC05-PC / SLA
Study First Received: November 22, 2007
Last Updated: March 18, 2010
Health Authority: France: Afssaps - French Health Products Safety Agency

Keywords provided by University Hospital, Tours:
neurology
sclerosis
imaging
tomography

Additional relevant MeSH terms:

Amyotrophic Lateral Sclerosis
Sclerosis
Spinal Diseases
Motor Neuron Disease
Spinal Cord Diseases
Central Nervous System Diseases
Nervous System Diseases
Neurodegenerative Diseases
Neuromuscular Diseases
Pathologic Processes
Bone Diseases
Musculoskeletal Diseases

ClinicalTrials.gov processed this record on August 04, 2010