Study of Rifaximin in Minimal Hepatic Encephalopathy

This study has been completed.

<table>
<thead>
<tr>
<th>Sponsor:</th>
<th>Hunter Holmes Mcguire Veteran Affairs Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaborators:</td>
<td>Salix Pharmaceuticals</td>
</tr>
<tr>
<td>Information provided by (Responsible Party):</td>
<td>Jasmohan Bajaj, Hunter Holmes Mcguire Veteran Affairs Medical Center</td>
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<tr>
<td>ClinicalTrials.gov Identifier:</td>
<td>NCT01069133</td>
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Purpose

Rifaximin therapy will improve brain functioning on MRI scanning and change the microbiome and metabolome.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
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<tbody>
<tr>
<td>Minimal Hepatic Encephalopathy</td>
<td>Drug: Rifaximin Drug: rifaximin</td>
<td>Phase 1/Phase 2</td>
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</table>

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, Non-Randomized
Official Title: Effect of Rifaximin Therapy on Brain Activation in Patients With Minimal Hepatic Encephalopathy Using Functional MR, MR Spectroscopy, Diffusion Tensor Imaging Microbiome and Metabolome: a Prospective Trial

Further study details as provided by Jasmohan Bajaj, Hunter Holmes Mcguire Veteran Affairs Medical Center:
Primary Outcome Measure:
• brain activation on fMRI [Time Frame: 2 months] [Designated as safety issue: No]
• Microbiome constituents [Time Frame: 8 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:
• brain edema and brain metabolite concentration [Time Frame: 2 months] [Designated as safety issue: No]
• Metabolome of urine and serum [Time Frame: 8 weeks] [Designated as safety issue: No]

Enrollment: 20
Study Start Date: February 2010
Study Completion Date: December 2012
Primary Completion Date: May 2012

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: Rifaximin</td>
<td>Drug: Rifaximin</td>
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<tr>
<td></td>
<td>550mg BID open-label</td>
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<td></td>
<td>Other Names:</td>
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<tr>
<td></td>
<td>xifaxan</td>
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<tr>
<td></td>
<td>Drug: rifaximin</td>
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Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both

Inclusion Criteria:

• Age 18-65 years
• cirrhosis diagnosed by clinical or biopsy grounds
• Minimal hepatic encephalopathy defined by impaired performance on at least 2 of the following: number connection tests A/B, digit symbol and block design tests (NCT-A, NCT-B, DST and BDT) compared to age and education-matched controls.
• No contraindications to MRI
• TIPS (transjugular intra-hepatic porto-systemic shunt) procedure or elective surgery planned within the next 8 weeks

Exclusion Criteria:

• Current therapy with lactulose, rifaximin or other treatment for hepatic encephalopathy.
• Prior episodes of overt HE
• MMSE <25
• TIPS placement
• Unable to give informed consent.
• Contra-indications to MRI

## Contacts and Locations

### Locations

**United States, Virginia**
Hunter Holmes McGuire VA Medical Center  
Richmond, Virginia, United States, 23249

### Investigators

**Principal Investigator:** Jasmohan S Bajaj, MD, MSc  
McGuire VA Medical Center

## More Information

**Responsible Party:** Jasmohan Bajaj, Associate Professor of Medicine, Hunter Holmes  
Mcguire Veteran Affairs Medical Center

**Study ID Numbers:** BAJAJ010

**Health Authority:** United States: Food and Drug Administration