Recombinant Factor VIIa in Acute Intracerebral Haemorrhage

This trial is conducted in Asia, Europe, Middle East, North America, Oceania, and South America.

The purpose of this study is to evaluate the treatment of Recombinant Factor VIIa (eptacog alfa (activated)) in patients with acute intracerebral bleeding. It is expected that more patients will recover without severe permanent disability after acute treatment with Recombinant Factor VIIa by reducing further intracerebral bleeding.

**Scientific Title**
Randomised, Double-Blind, Placebo Controlled, Multi-Centre, Parallel Groups Confirmatory Efficacy and Safety Trial of Activated Recombinant Factor VII (NovoSeven®/Niastase®) in Acute Intracerebral Haemorrhage

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<table>
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<tr>
<th>Trial IDs and acronym(s)</th>
<th>Condition</th>
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<tbody>
<tr>
<td><strong>Novo Nordisk Trial ID</strong></td>
<td>Intracerebral Haemorrhage</td>
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<tr>
<td>F7ICH-1641</td>
<td>Acquired bleeding disorder</td>
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<td><strong>Clinical Trials.gov Registration</strong></td>
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<td><strong>Other Identifier(s)</strong></td>
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<td>EudraCT Number: 2004-004202-24</td>
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<td>FAST</td>
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<table>
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<tr>
<th>Trial dates</th>
<th>Trial phase</th>
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<tbody>
<tr>
<td>Start date: 11.May.2005</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Primary completion date: 31.Jan.2007</td>
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<td>Completion date: 31.Jan.2007</td>
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<tr>
<th>Treatment</th>
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<tr>
<td>• eptacog alfa (activated)</td>
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<th>Arm Information with Assigned Treatment</th>
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<td>No. of arms: Not applicable</td>
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<table>
<thead>
<tr>
<th>Trial status</th>
<th>No. of trial participants</th>
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<tr>
<th>Age eligible for trial participation</th>
<th>Genders eligible for trial participation</th>
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<tr>
<td>18 Years and above</td>
<td>Both</td>
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<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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http://www.novonordisk-trials.com
- Spontaneous intracranial hemorrhage (ICH) within 3 hours after first symptom
- Patients with secondary ICH
- Pre-existing disability
- Haemophilia

**Trial type**
Interventional

**Trial design**
Purpose: Treatment
Allocation: Randomized
Masking: Double blind
Control: Placebo Control
Assignment: Parallel Assignment
Endpoint: Safety/Efficacy Study

**Primary outcome**
- Reducing disability and improving clinical outcome
  Time frame: After 3 months

**Secondary outcome(s)**
- Reducing mortality
- Reducing hematoma growth

**Participating countries**
- Australia: Completed
- Austria: Completed
- Belgium: Completed
- Brazil: Completed
- Canada: Completed
- China: Completed
- Croatia: Completed
- Denmark: Completed
- Finland: Completed
- France: Completed
- Germany: Completed
- Israel: Completed
- Italy: Completed
- Netherlands: Completed
- Norway: Completed
- Singapore: Completed
- Spain: Completed
- Sweden: Completed
- Taiwan: Completed
- Thailand: Completed
- United States: Completed

**Health authority approval obtained from**
- Australia: Department of Health and Ageing Therapeutic Goods Administration
- Austria: Federal Ministry for Health and Women
- Brazil: National Health Suveillance Agency
- Canada: Health Canada
- China: State Food and Drug Administration

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[http://www.novonordisk-trials.com](http://www.novonordisk-trials.com)
Croatia: Ministry of Health and Social Care  
Denmark: Danish Medicines Agency  
Finland: National Agency for Medicines  
France: Afssaps - French Health Products Safety Agency  
Germany: Paul-Ehrlich-Institut  
Hong Kong: Department of Health  
Israel: Israeli Health Ministry Pharmaceutical Administration  
Italy: National Monitoring Centre for Clinical Trials - Ministry of Health  
Netherlands: Dutch Health Care Inspectorate  
Norway: Norwegian Medicines Agency  
Singapore: Health Sciences Authority  
Spain: Spanish Agency of Medicines  
Sweden: Medical Products Agency  
Taiwan: Department of Health  
Thailand: Khon Kaen University Ethics Committee for Human Research  
United States: Food and Drug Administration  

**Central contact information**  
Trial sponsored by: Novo Nordisk A/S  
Contact: clinicaltrials@novonordisk.com  
For trials conducted in the US: (+1) 866-867-7178  

**Study director**  
Name: Global Clinical Registry (GCR, 1452)  
Novo Nordisk affiliation: Novo Nordisk A/S  

**Scientific trial publications**  
- Mayer SA, Brun NC, Begtrup K, Broderick JP, Davis SM, Diringer MN, Skolnick BE, Steiner T; on behalf of the FAST Investigators. Randomized, placebo-controlled, double-blind, multicenter phase III study to assess rFVIIa efficacy in acute intracerebral hemorrhage: the FAST trial. American Academy of Neurology (AAN) 2007; Country: USA, City: Boston, MA  
- Mayer SA, Brun NC, Begtrup K, Broderick JP, Davis SM, Diringer MN, Skolnick BE, Steiner T on behalf of the FAST Investigators. Randomized, placebo-controlled, double-blind phase III study to assess rFVIIa efficacy in acute intracerebral hemorrhage: the FAST trial. Cerebrovascular Diseases 2007; 23 (Suppl. 2): 10  

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358 (20): 2127-37

Labeling Information
• EU:
• US: http://www.fda.gov/BiologicsBloodVaccines/ucm133705.htm

Information provided by Novo Nordisk A/S
Protocol Information Published: 03.Aug.2005

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