Recombinant Factor VIIa in Acute Intracerebral Haemorrhage

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

The purpose of this study is to evaluate safety and efficacy of Recombinant Factor VIIa in patients with acute intracerebral bleeding.

**Scientific Title**
Randomised, Double-Blind, Placebo-Controlled, Multi-centre, Parallel Groups, Study to Evaluate the Efficacy and Safety of Activated Recombinant Factor VII (NovoSeven®) in Acute Intracerebral Haemorrhage

<table>
<thead>
<tr>
<th>Trial IDs and acronym(s)</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Novo Nordisk Trial ID</strong></td>
<td>Intracerebral Haemorrhage</td>
</tr>
<tr>
<td>F7ICH-1371</td>
<td>Acquired bleeding disorder</td>
</tr>
<tr>
<td><strong>Clinical Trials.gov Registration</strong></td>
<td></td>
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<tr>
<td>NCT00426803</td>
<td></td>
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<tr>
<td><strong>Other Identifier(s)</strong></td>
<td></td>
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<table>
<thead>
<tr>
<th><strong>Trial dates</strong></th>
<th><strong>Trial phase</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Start date: 29.Aug.2002</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Primary completion date: 03.Jun.2004</td>
<td></td>
</tr>
<tr>
<td>Completion date: 03.Jun.2004</td>
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</tbody>
</table>

**Treatment**
- activated recombinant human factor VII

**Arm Information with Assigned Treatment**
No. of arms: Not applicable

<table>
<thead>
<tr>
<th><strong>Trial status</strong></th>
<th><strong>No. of trial participants</strong></th>
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<tbody>
<tr>
<td>Completed</td>
<td>400</td>
</tr>
</tbody>
</table>

**Age eligible for trial participation**
18 Years and above

**Genders eligible for trial participation**
Both

**Inclusion criteria**
- Spontaneous intracranial haemorrhage (ICH) within 3 hours after first symptom

**Exclusion criteria**
- Patients with secondary ICH
- Pre-existing disability
- Haemophilia

<table>
<thead>
<tr>
<th><strong>Trial type</strong></th>
<th><strong>Trial design</strong></th>
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<tbody>
<tr>
<td>Interventional</td>
<td>Purpose: Treatment</td>
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</table>

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http://www.novonordisk-trials.com
<table>
<thead>
<tr>
<th>Primary outcome</th>
<th>Secondary outcome(s)</th>
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<tbody>
<tr>
<td>• Reducing haematoma growth</td>
<td>• Reducing disability and improving clinical outcome</td>
</tr>
</tbody>
</table>

**Participating countries**
- Australia: Completed
- Austria: Completed
- Belgium: Completed
- Canada: Completed
- Croatia: Completed
- Denmark: Completed
- Finland: Completed
- Germany: Completed
- Italy: Completed
- Malaysia: Completed
- Netherlands: Completed
- New Zealand: Completed
- Norway: Completed
- Singapore: Completed
- Spain: Completed
- Sweden: Completed
- Switzerland: Completed
- Taiwan: Completed
- United Kingdom: 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
- Canada: Health Canada
- Croatia: Ministry of Health and Social Care
- Denmark: Danish Medicines Agency
- Finland: National Agency for Medicines
- Germany: Paul-Ehrlich-Institut
- Italy: National Monitoring Centre for Clinical Trials - Ministry of Health
- Malaysia: Ministry of Health
- Netherlands: Dutch Health Care Inspectorate
- New Zealand: Food Safety Authority
- Norway: Norwegian Medicines Agency
- Singapore: Health Sciences Authority

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http://www.novonordisk-trials.com
Trial sponsored by: Novo Nordisk A/S

For trials conducted in the US: (+1) 866-867-7178

Study director
Name: Nicolai C. Brun, MD, Ph.D
Novo Nordisk affiliation: Novo Nordisk A/S

Scientific trial publications
- Diringer MN, Skolnick BE, Mayer SA, Steiner T, Davis SM, Brun NC, Broderick JP. Risk of Thromboembolic Events in Controlled Trials of rFVIIa in Spontaneous Intracerebral Hemorrhage. Stroke 2008; 39: 850-856

Labeling information
- EU:
Information provided by Novo Nordisk A/S

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