Early detection of Stroke

DIASTROKE®
Glycogen Phosphorylase Isoenzyme BB
Background
Cerebrovascular disease is the third most common cause of death worldwide. According to official WHO data, around six million people die from it every year. However, there still is no such thing as an early biomarker that can reliably diagnose a stroke.

New Possibilities
Diagenics SE has now developed a method to measure a new biomarker for stroke: Glycogen Phosphorylase isoenzyme BB (GPBB). This enzyme is specific for heart and brain tissue, and in case of an ischemia it is immediately released into the blood stream - much earlier than any necrosis marker.

Studies
Diagenics SE owns the proprietary antibodies to this enzyme and has already developed a product line for the early diagnosis of stroke: Diastroke™. The product has been CE registred by the abovementioned study. Further studies will increase our knowledge related to the diagnosis of stroke.

Product
Diastroke POCT [DS - P3] is a diagnostic device for the specific and early diagnosis of a stroke by the detection of GPBB in human blood or plasma.

Format
A point of care test (POCT) for early and reliable detection of a stroke, based on the marker Glycogen Phosphorylase isoenzyme BB (GPBB).

Mode of Operation
Diastroke POCT qualitatively detects the enzyme GPBB that is released into the blood due to cerebral ischemia. Utilizing whole blood or plasma, the Diastroke POCT gives a solid answer on a patient’s state shortly after symptom onset.

System
As a Lateral flow test, the enzyme based immunoassay provides reliable results within 15 minutes.

CE-Approved
Time of approval: Q4/2012

Partner
The CE-certified production partner for the Diastroke POCT system is VEDA.LAB, France.

Product
Diastroke ELISA (Enzyme linked Immuno sorbent Assay) [DS-E2] is a diagnostic device for the specific and early detection of a stroke.

Format
ELISA for the measurement of the brain-specific ischemia marker Glycogen Phosphorylase isoenzyme BB (GPBB) to reliably detect strokes.

Mode of Operation
Diastroke ELISA quantitatively detects the enzyme GPBB which is released into the blood from ischemic brain cells. Abnormally elevated GPBB blood levels shortly after typical symptom onset indicate a stroke.

System
96-well microtiter plates, enzyme immunoassay (Sandwich ELISA) that is compatible with standard ELISA reader systems.

CE-Approved
Time of approval: Q4/2012

Partner
The CE-certified production partner for the Diastroke ELISA system is Viro-Immun GmbH, Germany.

Product
After having performed a Diastroke POCT, the respective test stripe is inserted into the device holder of the Diastroke Reader [DX - R1]. The reader analyzes the POCT within 1 minute regarding test and control line. The intensity of the test line is measured and translated into the GPBB concentration of the analyzed sample. The results are displayed and documented.

Format
An optical reader to document and store the result of the POCT (Point-of-care-test).

CE-Approved
Time of approval: tba

Partner
The CE-certified production partner for the Diastroke READER is the company opTricon GmbH, Germany.

* The test result should only be interpreted by medical specialists in conjunction with the patient’s history, clinical symptoms and other medical investigations (blood values, electrocardiogram and imaging) according to the latest guideline for stroke. Also considering the guideline for stroke differential diagnostic procedures should be used to eliminate myocardial infarction, a condition that also causes high GPBB levels. Special attention should be taken with pregnant women, because in pregnancy levels of GPBB in the blood can be increased.
CLINICAL EVALUATION

GPBB assessment in patients with acute stroke

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Stroke 9h</th>
<th>Stroke 48h</th>
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<tbody>
<tr>
<td>Quantity of persons</td>
<td>97</td>
<td>172</td>
<td>172</td>
</tr>
<tr>
<td>GPBB [ng/ml]</td>
<td>4.8±8.0</td>
<td>46.3±38.6</td>
<td>38.7±36.5</td>
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<tr>
<td>p vs. control</td>
<td>0.001</td>
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<tr>
<td>ROC</td>
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</tbody>
</table>

Source:
"A new biomarker for diagnosis of ischemic stroke: Plasma Glycogen Phosphorylase", Abstract 2012. Autors: Ross Avery, Alfredo Caceres, Kwang Yeol Park, Swetlana Lorenzano, Ilknur Ay, Ferdinando S. Buoanno, Karen L. Furie, Hakan Ay Martins Center for Biomedical Imaging, Department of Radiology, Massachusetts General Hospital, Harvard Medical School, Boston MA; and Department of Neurology, Massachusetts General Hospital, Harvard Medical School, Boston MA, Massachusetts General Hospital, Harvard Medical School, Boston MA

Background:
Glycogen phosphorylase-BB (GPBB) is the key enzyme that breaks down glycogen to yield glucose-1-phosphate in order to meet the emergent need for ATP during cerebral ischemia. GPBB is one of the most sensitive and specific plasma markers for early detection of acute myocardial ischemia. The brain concentration of GPBB is about 100 times higher than that in the heart. It was hypothesized that plasma levels of GPBB might also elevate following cerebral ischemia.

Conclusion:
Plasma GPBB appears to be a sensitive and specific marker for early diagnosis of ischemic stroke. The lack of correlation with infarct volume and high proportional rise with respect to the discriminator value suggest that GPBB may find utility particularly in diagnosis of mild stroke syndromes associated with trace amounts of brain injury.

Contact

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