Thrombin Generation and Thrombus Degradation in Cerebral Venous Thrombosis : Clinical and Radiological Correlations (PHRC-TVC)

This study is currently recruiting participants. (see Contacts and Locations)
Verified July 2015 by University Hospital, Rouen
Sponsor:
University Hospital, Rouen
Information provided by (Responsible Party):
University Hospital, Rouen
ClinicalTrials.gov Identifier:
NCT02013635
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History of Changes

- Full Text View
- Tabular View
- No Study Results Posted
- Disclaimer
- How to Read a Study Record

Purpose

Cerebral venous thrombosis is considered as a rare type of stroke with an annual incidence of 3 to 4 per million people. It occurs generally in young patients (mean age of occurrence = 40 years) and principally in young females (75%) generally in pregnancy or oral contraceptive use situations.

The onset may be acute (less than 2 days), subacute (between 2 and 30 days) or chronic (more than 30 days). The clinical presentation is highly variable and includes patients with only a mild headache, others with focal neurological deficits and a few with a dramatic syndrome and a coma. Moreover the evolution can be very different with unpredictable outcome: more often it is favorable with a low mortality rate, but in some cases it can be a worse course. The aim of this study is to evaluate the correlation of some biological markers: thrombin generation test and D-Dimers (marker of fibrin generation and degradation) with the type of onset or the wide spectrum of clinical presentations or the different modes of evolution.

All patients over 16 years ago may be included in the program when CVT diagnosis is proved by magnetic resonance angiography (MRA). For each included patient, there are four blood assays: the first just at the time of diagnosis and before the beginning of treatment, the second before the beginning of the oral anticoagulant treatment. The third assay is done in the third month at the time of a MRA. The last assay is made one month after the end of the anticoagulant treatment or in 12th month after the beginning of the disease if the treatment goes on.

For each sample, the investigators perform a thrombin generation test and a D-Dimers measurement.

Condition
Cerebral Venous Thrombosis

Study Type: Observational

Study Design: Observational Model: Case-Only
Time Perspective: Prospective

Official Title: Study of Thrombin Generation and Thrombus Degradation in Cerebral Venous Thrombosis : Correlation With Clinical and Radiological Evolution

Resource links provided by NLM:

MedlinePlus related topics: Deep Vein Thrombosis
Drug Information available for: Prothrombin Thrombin
U.S. FDA Resources

Further study details as provided by University Hospital, Rouen:

Primary Outcome Measures:

- Evolution of thrombin generation parameters [Time Frame: one year]
  [Designated as safety issue: No]

  Evolution from Baseline in thrombin generation parameters and correlation with clinical presentation (initial state and severity with NIH stroke scale and GLASGOW Scale)

- Evolution of D Dimers concentration [Time Frame: one year]
  [Designated as safety issue: No]

  Evolution from Baseline in D Dimers concentration and correlation with clinical presentation (initial state and severity with NIH stroke scale and GLASGOW Scale)

Secondary Outcome Measures:

- Evolution of thrombin generation parameters after end of treatment [Time Frame: one year] [Designated as safety issue: No]

  Evolution from end of treatment in thrombin generation parameters and correlation with clinical presentation (initial state and severity with NIH stroke scale and GLASGOW Scale)

- MR Imaging and Thrombin generation parameters [Time Frame: one year]
  [Designated as safety issue: No]

  Number of venous occlusions on MR Imaging and correlation with thrombin generation parameters

- MR Imaging and D Dimers concentration [Time Frame: one year]
  [Designated as safety issue: No]

  Number of venous occlusions on MR Imaging and correlation with D Dimers concentration

- Evolution of D Dimers concentration after treatment [Time Frame: one year]
  [Designated as safety issue: No]

  Evolution from end of treatment in D Dimers concentration and correlation with clinical presentation (initial state and severity with NIH stroke scale and GLASGOW Scale)

Biospecimen Retention: Samples With DNA
plasma, serum and whole blood

Estimated Enrollment:	250
Study Start Date:	July 2011
Estimated Study Completion Date:	September 2016
Estimated Primary Completion Date:	September 2016 (Final data collection date for primary outcome measure)

Groups/Cohorts
Cerebral Venous Thrombosis patients over 16 years old with acute cerebral venous thrombosis

Eligibility

Ages Eligible for Study:	16 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Probability Sample

Study Population
Patients over 16 years old hospitalized with an acute cerebral venous thrombosis
Criteria

Inclusion Criteria:

- Patients over 16 years old hospitalized with an acute cerebral venous thrombosis, confirmed by by cerebral imaging

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02013635

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More Information

No publications provided

Responsible Party:	University Hospital, Rouen
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Study First Received:	November 28, 2011
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cerebral venous thrombosis
thrombin generation
d-dimers
clinical evolution

Additional relevant MeSH terms:

Thrombosis	Thrombin
Venous Thromboembolism	Coagulants
Venous Thrombosis	Hematologic Agents
Cardiovascular Diseases	Hemostatics
Embolism and Thrombosis	Pharmacologic Actions
Thromboembolism	Therapeutic Uses
Vascular Diseases	

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