

Frequency and characterisation of stroke rehabilitation in an unselected group of young stroke patients with Fabry disease

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Registration date 27/02/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/01/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00413595

ClinicalTrials.gov (NCT)
NCT00414583

Protocol serial number

Study information

Scientific Title

Frequency and characterisation of stroke rehabilitation in an unselected group of young stroke patients with Fabry disease: a prevalence study

Acronym

SIFAP

Study objectives

To analyse the frequency of Fabry disease in an unselected group of cardiovascular event (CVE) patients aged between 18 and 55 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Germany: Ethics Committee of the Medical Association Mecklenburg-Vorpommern (Board 2), University of Rostock, gave approval on the 14th September 2006. All other centres will seek ethics approval before recruiting participants.

Study design

Observational, cohort, prevalence study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Fabry disease and stroke

Interventions

Any participant who is eligible for entry to the study and has signed informed consent will have 20 ml of blood taken at baseline (V0). The following assessments will then be performed at the following timepoints:

1. Medical status (physical examination, clinical symptoms): V0 - V12
2. Enzyme replacement therapy/concomitant medication: V0 - V12
3. Adversene events/premature study termination: V1 - V12
4. Gb3 antibody levels: V0 - V12
5. Clinical chemistry: V0, V2, V4, V6, V8, V10, V12
6. Stroke classification:
 - 6.1. Modified Rankin Scale (mRS): V0
 - 6.2. TOAST criteria: V0
 - 6.3. NIHSS: V0, V2, V4, V6, V8, V10, V12
 - 6.4. Barthel Index: V0
7. Neuropsychological testing:

- 7.1. Mini-Mental State Examination (MMSE): V0 - V12
- 7.2. 36-item Short Form Health Survey (SF36): V0 - V12
- 7.3. Beck Depression Inventory II (BDI II): V0 - V12
- 7.4. Brief Pain Inventory (BPI): V0 - V12
8. Rostocker - Kopfschmerzfragen - Komplex (RoKoKo) (Austrian and German centres only) and Habi Test (Rostock centre only): V0, V2, V4, V6, V8, V10, V12
9. Electrocardiogram and echocardiography: V0, V4, B8, V12
10. Cardiac magnetic resonance imaging (MRI): V0, V12
11. Cerebral MRI: V0, V3, V6, V9, V12
12. Colour-coded duplex sonography/transcranial doppler sonography (TCD): V0, V2, V4, V6, V8, V10, V12
13. Renal sonography: V0, V2, V4, V6, V8, V10, V12
14. Ophthalmological investigation: V0, V4, V8, V12

Timepoints are as follows:

V0: Baseline

V1: 4 months after baseline

V2: 8 months after baseline

V3: 12 months after baseline

V4: 16 months after baseline

V5: 20 months after baseline

V6: 24 months after baseline

V7: 28 months after baseline

V8: 32 months after baseline

V9: 36 months after baseline

V10: 40 months after baseline

V11: 44 months after baseline

V12: 54 months after baseline (final visit)

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Frequency of patients with Fabry disease in a cohort of acute stroke patients

Key secondary outcome(s)

The classification of stroke sub-type and degree of severity of stroke in patients identified to have Fabry disease according to:

1. TOAST (Trial of ORG 10172 in Acute Stroke Treatment) criteria (according to Adams, 1993)
2. Modified Rankin Scale for severity of stroke
3. Barthel Index
4. Magnetic Resonance Imaging (MRI) criteria

Completion date

30/06/2009

Eligibility

Key inclusion criteria

1. Adult patients (18 - 55 years of age, either sex) with an acute cerebrovascular event of any aetiology defined as patients having an acute ischaemic stroke or transient ischaemic attack less than 3 months before enrolment into the study
2. Magnetic resonance imaging (MRI)-scan evidence of associated corresponding brain infarction or haemorrhage, regardless of the duration of symptoms. Alternatively also patients with no signs of stroke in the MRI can be included if a stroke-experienced neurologist has done the initial diagnosis as ischaemic stroke, transient ischaemic attack or haemorrhage.
3. Detailed MRI documentation at admission to entry to the study
4. Diagnostic procedures for CVE according to the European Stroke Initiative (EUSI) recommendations
5. Written informed consent from patient or legal representative according to local regulations

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients being younger than 18 years or older than 55 years of age
2. Acute ischaemic stroke or transient ischaemic attack longer than 3 months before enrolment into the study
3. Diagnosis of the 3-month lasting CVE has been done by a non-neurologist if there is no MRI-scan evidence of associated brain infarction or haemorrhage
4. No detailed MRI documentation at admission to entry to the study

Date of first enrolment

01/04/2007

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

United Kingdom

Austria

Belgium

Croatia

Finland

France

Georgia

Germany

Ireland

Italy

Malta

Poland

Portugal

Spain

Study participating centre

Albrecht-Kossel-Institute for Neuroregeneration

Rostock

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Sponsor information

Organisation

Albrecht-Kossel-Institute for Neuroregeneration (Germany)

ROR

<https://ror.org/03zdwsf69>

Funder(s)

Funder type

Industry

Funder Name

Shire Human Genetic Therapies, Inc (USA) - unrestricted educational grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2013		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes