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

Submission date	Recruitment status
13/01/2009	No longer recruiting
Registration date	**Overall study status**
27/02/2009	Completed
Last Edited	**Condition category**
15/01/2013	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.sifap.de/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00414583

Secondary identifying numbers
II PV 03/2006; II PV 04/2006 (NCT00413595)

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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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. Opthalmological 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 measure
Frequency of patients with Fabry disease in a cohort of acute stroke patients

Secondary outcome measures
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

Overall study start date
01/04/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
5000

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
Austria

Belgium

Croatia

Finland

France

Georgia

Germany

Ireland

Italy

Malta

Poland

Portugal

Spain

United Kingdom

Study participating centre
Albrecht-Kossel-Institute for Neuroregeneration
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Sponsor information

Organisation
Albrecht-Kossel-Institute for Neuroregeneration (Germany)

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Sponsor type
Research organisation

Website
http://albrecht-kossel-institut.de

ROR
https://ror.org/03zdwsf69

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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