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Are certain forms of the P2Y2 gene associated with the risk of stroke in northern Han Chinese people?

Submission date
15/10/2018

Recruitment status
No longer recruiting

Registration date
24/10/2018

Overall study status
Completed

Last Edited
13/12/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
People in northern China are at an increased risk of ischemic stroke (damage to the brain caused by narrowing of blood vessels in the brain). This study aimed to investigate if gene forms linked to increased risk of stroke are more common in Han Chinese people in this region.

Who can participate?
People aged 45-80 years who had had an ischemic stroke and healthy volunteers matched in terms of age, gender, ethnic group and area of residence with the stroke group.

What does the study involve?
One sample of blood was taken from a vein (usually in the arm).

What are the possible benefits and risks of participating?
There was the potential for discomfort when the blood was taken. There are no potential benefits of taking part.

Where is the study run from?
The First Affiliated Hospital of China Medical University.

When is the study starting and how long is it expected to run for?
The samples were collected from September 2010 to May 2011 and the data analysed from March 2012 to April 2012.

Who is funding the study?
This study was supported by a grant from the National Natural Science Foundation of China, No. 81070913.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
G-Protein Coupled Purinergic Receptor P2Y2 (P2RY2) gene rs4944832 polymorphism increases the risk of ischemic stroke in the northern Han Chinese population

Study objectives
The G-C-G haplotype of P2RY2 is a susceptibility haplotype for ischemic stroke. In addition, the GG genotype of rs4944832 may be associated with the development of small-artery occlusion in the northern Han Chinese population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the First Affiliated Hospital of China Medical University, 20/02/2012, 2012-38-1
2. Ethics Committee of the First Affiliated Hospital of Liaoning Medical University, 01/03/2013, 2013-03-1

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Ischemic stroke

Interventions
In this study, clinical data and peripheral blood specimens were collected from ischemic stroke patients and controls. The ischemic stroke participants were recruited from the First Affiliated Hospital of China Medical University and the First Affiliated Hospital of Liaoning Medical University. The controls were recruited from the Health Check Center at the First Affiliated Hospital of China Medical University. Ischemic stroke patients were divided into two subgroups according to the Trial of ORG 10172 in Acute Stroke Treatment (TOAST) classification: large-artery atherosclerosis (n = 178) and small-artery occlusion (n = 200) strokes. All subjects were genotyped using SNaPshot® Multiplex (Thermo Fisher Scientific) for three single-nucleotide polymorphisms in the P2RY2 gene (rs4944831, rs1783596 and rs4944832) in peripheral venous blood.

Intervention Type
Genetic

Primary outcome measure
The genotype frequencies of the three P2RY2 SNPs (rs4944831, rs1783596, and rs4944832) in ischemic stroke patients and controls.

Secondary outcome measures
1. Allele frequencies of the three P2RY2 SNPs (rs4944831, rs1783596, and rs4944832) in ischemic stroke patients and controls.
2. Inferred haplotypes of these three P2RY2 SNPs (rs4944831, rs1783596, and rs4944832).

Overall study start date
01/05/2010

Completion date
30/04/2012

Eligibility

Key inclusion criteria
Inclusion criteria for the ischemic stroke group:
1. According to the TOAST classification, patients in the ischemic stroke group were diagnosed depending on clinical features and neuroimaging criteria that included the sudden onset of a global or focal neurological deficit, with corresponding brain infarction as seen on computed tomography (CT) imaging or magnetic resonance imaging (MRI) (Adams et al., 1993). Examinations of cerebral blood vessels, such as computed tomography angiography and magnetic resonance angiography, were performed when necessary.

Inclusion criteria for the control group:
1. Unrelated healthy controls with no clinical or radiological evidence of stroke or cerebrovascular diseases.
2. Some healthy controls had vascular risk factors such as hypertension, diabetes, smoking, drinking, and hypercholesterolemia.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
722

Key exclusion criteria
Exclusion criteria for the ischemic stroke group:
1. Cancer
2. Hemorrhagic stroke
3. Transient ischemic attack
4. Severe cardiac, hepatic, or renal diseases

Exclusion criteria for control subjects:
1. Cancer
2. Autoimmune disease
3. Chronic inflammation
4. Renal insufficiency
5. Liver insufficiency
6. Hematopathy

Date of first enrolment
01/09/2010

Date of final enrolment
30/05/2011

Locations

Countries of recruitment
China

Study participating centre
The First Hospital of China Medical University
No.155, Nanjing North Street, Heping District
Shenyang
China
110000

Study participating centre
The First Affiliated Hospital of Liaoning Medical University
No.2, Section 5, Renmin Street, Guta District
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Sponsor information

Organisation
the First Hospital of China Medical University

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04wjghj95

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Publication and dissemination plan

Intention to publish date
17/04/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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	01/03/2019		Yes	No