MicroRNA as biomarker for acute stroke

Published: 18-05-2018
Last updated: 12-04-2024

Our primary objective is to test temporal microRNA profiles in patients presented by the emergency services to the emergency room with a suspicion of acute (i.e.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON55785

Source
ToetsingOnline

Brief title
MicroRNA as biomarker for acute stroke

Condition

- Central nervous system vascular disorders

Synonym
cerebral hemorrhage, cerebral infarction, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlandse hartstichting

Intervention

Keyword: biomarker, microRNA, stroke

Outcome measures

Primary outcome

In-between differences in microRNA profiles on admission to the emergency

department and within differences in each group in time.

Secondary outcome

clinical characteristics and radiological outcomes of the patients (all

gathered in routine clinical practice)

Study description

Background summary

Diagnosis of ischemic stroke should be rapid for clinical efficacy of reperfusion therapy and reliable in order not to miss stroke patients or expose non-stroke patients to reperfusion related complications. Currently stroke diagnosis is time consuming with a low specificity. Recently micro-RNA*s have showed to be very promising as a stroke biomarker but was never compared in acute ischemic stroke patients, haemorrhagic stroke patients or stroke mimics (i.e. stroke simulating conditions). We hypothesize that (a combination of) specific (freely circulating) microRNA*s can be used as biomarkers to establish diagnosis of acute ischemic stroke.

Study objective

Our primary objective is to test temporal microRNA profiles in patients presented by the emergency services to the emergency room with a suspicion of acute (i.e. <6 hours) ischemic stroke

Study design

observational study

Study burden and risks

Sampling of additional plasma for study purposes (2 x 10 ml per blood draw) will be done as much as possible within regular blood sampling as is part of routine care. We aim to sample plasma for study purposes on the following time

points (total: 4): admission, day 1 and 2-5 and after 6 to 8 weeks. In practice routine samples will be performed on admission for all patients (t=0) and day after admission for groups A and B (t=1). The study carries no inherent risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Patients considered potentially eligible by EMS personnel for IVT/IAT for whom a pre-
stroke alarm is initiated.
2) For patients included in the IS group: a National Institutes of Health Stroke Scale >=4 or eligible for reperfusion treatment
3) Age >=18 years
4) For patients included in the IS or HS group: clinical admission on the

neurology ward

Exclusion criteria

- Use of therapeutic heparin within 24 hours before onset of symptoms
- Extracranial malignancy (patients can be included if they have a prior history of malignancy if the patient received curative treatment)
- Alteplase treatment started

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2018
Enrollment:	430
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-01-2019

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-06-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	22-07-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63060.058.17