ISRCTN36126862 https://doi.org/10.1186/ISRCTN36126862

Endovascular treatment of cerebral vasospasm with milrinone and nimodipine

Submission date	Recruitment status	[ ] Prospectively registered
31/10/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/11/2018	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/06/2025	Circulatory System	

Plain English summary of protocol

Background and study aims
More than 800 people every year in Austria suffer from severe brain bleeding because of ruptured aneurysms. An aneurysm is a balloon-shaped bulging of an arterial vessel within the head. Up to 4% of the population carry an aneurysm, but not all of them rupture. After bleeding from a ruptured aneurysm, severe and potentially lethal complications may follow. One of this is the spastic narrowing of the brain vessels, which is where the blood vessels in the brain can suddenly constrict, leading to reduced blood supply of the brain. This is called a cerebral vasospasm. It leads to a high number of deaths and in survivors, leads to an intensive need for help in daily activities. Currently, there is no specific treatment for cerebral vasospasm. This study aims to look at the effectiveness of a new drug combination (milrinone and nimodipine) for cerebral vasospasm.

Who can participate?
Adults who have had cerebral vasospasm after an ruptured aneurysm and are being treated in Krankenanstalt Rudolfstiftung in Vienna, Austria

What does the study involve?
Participants will be given 2 mg nimodipine for 20 minutes, followed by 5 mg milrinone given over 30 minutes. Participants will stay in intensive care for at least 21 days and will be followed up within at least 6 weeks after discharge.

What are the possible benefits and risks of participating?
There are no known benefits or risks to participants taking part in this study. The only known side effect of the drugs used is low blood pressure; however, this side effect is not seen in the application of drugs used in this study.

Where is the study run from?
Krankenanstalt Rudolfstiftung, Vienna (Austria)

When is the study starting and how long is it expected to run for?
June 2012 to June 2017

Who is funding the study?
Krankenanstalt Rudolfstiftung (Austria)

Who is the main contact?
Dr. Bernhard Wambacher
bernhard.wambacher@wienkav.at

Contact information

Type(s)
Scientific

Contact name
Dr Bernhard Wambacher

Contact details
Juchgasse 25/NChir.
Vienna
Austria
1030

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4.1

Study information

Scientific Title
Repeated combined endovascular therapy with milrinone and nimodipine for the treatment of severe cerebral vasospasm

Study objectives
Repeated combined endovascular therapy with milrinone and nimodipine for the treatment of severe vasospasm improves neurological outcome and reduces mortality

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee of the City of Vienna (Ethikkommission der Stadt Wien), 12/02/2018, EK 16-227-VK-NIS

Study design

Interventional prospective single center non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Severe cerebral vasospasm

Interventions
All patients received endovascular therapy with 2 mg nimodipine infused over 20 minutes, followed by 5 mg milrinone infused over 30 minutes into the symptomatic vessels using an angiography catheter positioned extracranially/intra-arterially.
All patients were monitored in the intensive care department or an intermediate care set-up for the period they were in a critical condition, but at least up to day 21 after initial bleeding. A routine clinical follow-up was completed within 6 weeks after discharge.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nimodipine Milrinone

Primary outcome measure
Clinical outcome, assessed at the baseline, on the day of discharge and at least 6 weeks after, using the following:
1. Glasgow Outcome Score (GOS)
2. Modified Ranking Scale (mRS)

Secondary outcome measures
The following are assessed at the baseline, on the day of discharge and after 6 weeks:
1. Vessel diameter, assessed using the Centricity Universal Viewer through digital subtraction of the angiogram pre- and post-intervention
2. Transcranial Doppler (TCD) values, assessed using a standard transcranial Doppler sonography set

Overall study start date
01/06/2012

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Aneurysmal subarachnoid haemorrhage
2. Consecutive cerebral vasospasm
3. Treated in Krankenanstalt Rudolfstiftung during the observational period
4. Aged 18-85 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
38

Total final enrolment
38

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
01/01/2013

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
Austria

Study participating centre
Krankenanstalt Rudolfstiftung
Juchgasse 25, 1030
Vienna
Austria
1030

Sponsor information

Organisation
Cerebrovascular Research Group Vienna

Sponsor details
Juchgasse 25/Abteilung Neurochirurgie
Vienna
Austria
1030

Sponsor type
Research organisation

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication in the Journal of Critical Care as soon as possible

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available from 01/12/2019. Requests via email from Bernhard Wambacher (bernhard.wambacher@wienkav.at).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2025	16/06/2025	Yes	No