

# PROTECT-U

Prospective **R**andomized **O**pen-label **T**rial to **E**valuate risk **fa**CTor management  
in patients with **U**nruptured intracranial aneurysms

## NEWSLETTER 1 (June 2018)

### Principal investigators:

Prof. dr. Nima Etminan  
Dr. Mervyn Vergouwen

### Steering committee:

Prof. dr. Gabriel Rinkel  
Prof. dr. Ale Algra  
Prof. dr. Daniel Hänggi  
Prof. dr. Helmuth Steinmetz  
Prof. dr. Jens Fiehler  
Prof. dr. Peter Vajkoczy  
Dr. Frans Rutten

### Website:

[www.protect-u-trial.com](http://www.protect-u-trial.com)

Dear PROTECT-U investigators,

Hereby we send you the first newsletter of the PROTECT-U trial. After one year of preparations, the first patient was included in September 2017 in Mannheim. Since then, 11 out of 14 other German centers have been initiated. In April 2018, the first (UMC Utrecht) of a total of 6 Dutch centers was initiated. We are glad that now 57 patients have been included.

The purpose of the PROTECT-U trial is to investigate whether a medical treatment strategy consisting of acetylsalicylic acid 100mg/day plus intensive blood pressure treatment (targeted systolic blood pressure <120mmHg, monitored with a home blood pressure measuring device) reduces the risk of aneurysm rupture or growth compared with standard care (no acetylsalicylic acid, targeted systolic blood pressure <140mmHg, no home blood pressure measuring device).

We aim to randomize 776 patients 1:1 to either the intervention arm or standard care in 20 centers in Germany and the Netherlands. The primary outcome is aneurysm rupture or growth (increase in any aneurysm diameter by  $\geq 1$ mm) on repeated MR or CT angiography within  $36 \pm 6$  months after randomization. The trial has a PROBE design (prospective, randomized, open-label trial with blinded outcome assessment), and is registered at [clinicaltrials.gov](https://clinicaltrials.gov): NCT03063541.

We now also have a website, where you can quickly find all relevant information, such as the protocol, inclusion- and exclusion criteria, and links to the randomization tool and the eCRF.

We hope that in the coming weeks all other centers will be initiated, leading to many more patient inclusions. In the future we will keep you up-to-date through the website and newsletters. Please do not hesitate to contact us or the project manager PD Dr. Martin Koch (KKS Heidelberg, tel. +49-622156-39527) in case of any general questions regarding the trial conduct or the suitability of specific aneurysm patients for inclusion into the trial.

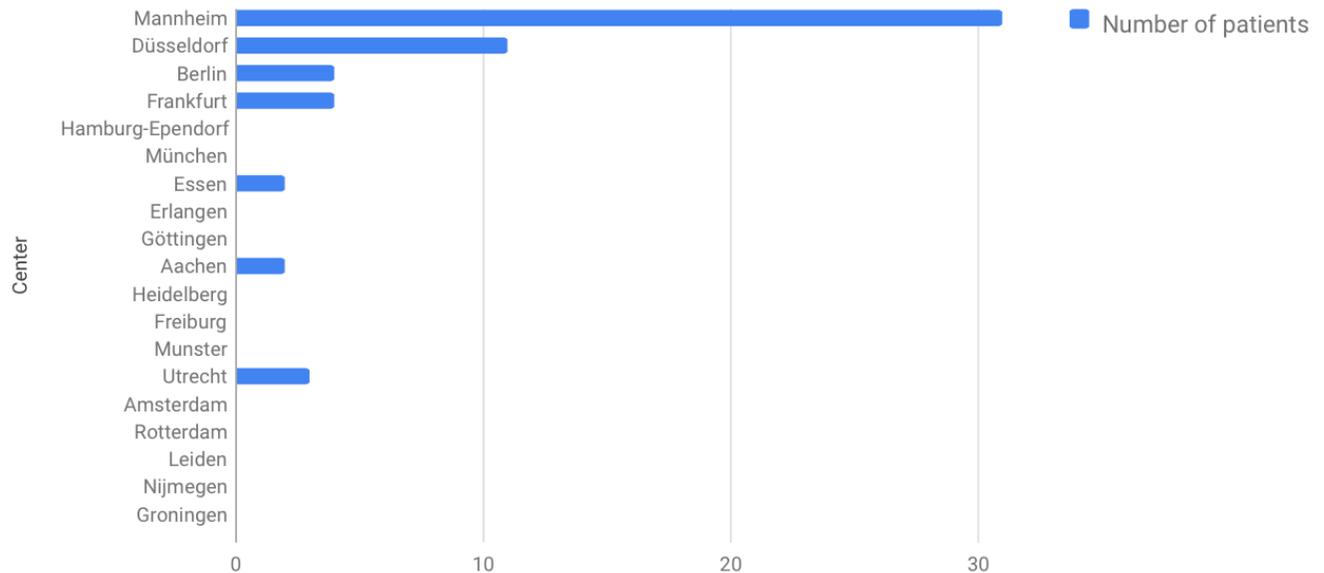
Kind regards, on behalf of the PROTECT-U team of investigators,

Nima Etminan  
Mervyn Vergouwen

# PROTECT-U

Prospective **R**andomized **O**pen-label **T**rial to **E**valuate risk **fa**CTOR management in patients with **U**nruptured intracranial aneurysms

Total number of included patients: 57 (last update June 13, 2018)





## Dr. Rolf M. Schwiete Stiftung



**UMM**  
UNIVERSITÄTSMEDIZIN  
MANNHEIM

Medizinische Fakultät Mannheim  
der Universität Heidelberg  
Universitätsklinikum Mannheim





**UMC Utrecht**



**KKS**  
Heidelberg  
Koordinierungszentrum  
für Klinische Studien



**eppdata**



**CAREONLINE**  
THE CARE CONTINUUM  
\* und mit freundlicher Unterstützung durch die Klinik  
für Strahlentherapie, Universitätsmedizin Mannheim