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**Amendment 7 for the EFFECTS study**

**EudraCT no: 2011-006130-16**

**EPN no: Ref. no: 2013/1265-31/2. Date 30/09/2013**

**Amendment 1: Date: 15/04/2015**

**Amendment 2: Ref. no: 2015/991-32. Date 10/06/2015**

**Amendment 3: Ref. no: 2015/20156-32. Date 30/11/2015**

**Amendment 4: Ref. no: 2016/1191-32. Date 14/06/2016**

**Amendment 5: Ref. no: 2016/2531-32. Date 04/01/2017**

**Amendment 6: Ref. no. 2017/638-32. Date 28/03/2017**

As a supplement to the already approved application, a resource letter is submitted for Hudiksvall Hospital.

For information purposes, we have switched PI in the following places: Rehab Station Stockholm (from Sabahudin Bjelak to Liisa Hopia), Stora Sköndal (from Mehran Taklif to Anna Sjöström), Norrtälje Hospital (Ann Engquist to Moa Gunnarsson). This has been updated in the delegation lists. We have closed the following centres: Visby, Högsbo, Lidköping Örebro and Bromma Geriatric Hospital. We will also change PI at Karolinska Hospital, Solna in the spring as I will be ending my employment there. I am currently on leave from my position as a senior consultant at Karolinska University Hospital in order to try out a corresponding role at Uppsala University Hospital. However, I am still affiliated with KI, just as before, but specialist doctor Bjarni Gudmundsson will assume responsibility as PI. Furthermore, we have not changed anything regarding sponsorship or finances – this remains at KI. All this is supported and approved by the EFFECTS steering committee and responsible head of department at KI, Professor Erik Näslund.

Previously, we submitted resource letters for: Danderyd Hospital, Karolinska Hospital (Solna), Hässleholm, Skaraborg Hospital Skövde, Uppsala University Hospital, Karolinska Hospital (Huddinge), Capio S:t Görans Hospital, Mora Hospital, Falu Hospital, Lidköping, Norrtälje, Kristianstad, Rehab Station Stockholm, Mälarsjukhuset Hospital Eskilstuna, Hallands Hospital Halmstad, Skåne University Hospital

Malmö, Helsingborg Hospital, Skåne University Hospital Lund, Norrland's University Hospital Umeå, Visby Hospital, Sundsvall Hospital, Sahlgrenska University Hospital Gothenburg, Högsbo Hospital Gothenburg, Stora Sköndal, Östersund Hospital, Alingsås Hospital, Ängelholm Hospital, Stockholm Sjukhem, Örebro University Hospital Rehab Medicine, Northern Älvsborg County Hospital Trollhättan, Bromma Geriatric Hospital, Västmanland Hospital Västerås, Dalen Hospital and Lindesberg Hospital.

### **Application for permission to pool variables with Riksstroke**

EFFECTS now has about one year left of inclusion. When we go through the variables we have collected, we notice that we have failed to include questions following a completed intravenous thrombolysis and thrombectomy. One alternative would be to go through all the patients' medical records, something that we are authorised to do, but it would be more effective to link this task with the quality register Riksstroke. The variables we require are:

1. Thrombolysis performed for stroke
2. Date of thrombolysis therapy
3. Thrombectomy or other catheter-based (endovascular) treatment for stroke
4. Date of thrombectomy

In addition, we also wish to have access to 4 variables prior to stroke (also taken from Riksstroke):

5. Need for assistance
6. Mobility
7. Toilet visits
8. Dressing

These variables form the basis of the algorithm that Riksstroke uses to assess the modified Ranking Scale. The purpose of linking these with the EFFECTS study is to examine how consistent the Riksstroke's algorithm is with the way we calculate the modified Ranking Scale in EFFECTS, namely the small modified Ranking Scale questionnaire (smRSq).

In order to facilitate the assessment of the study in the future, we have now updated the research plan with a version history – "Version history of the protocol". Previously, this version history has been documented in a separate document, but we believe that this increases transparency, updating the research plan to v 5.0.

### **Application to send a priority questionnaire to participants in the study**

When we planned the EFFECTS study, we intended to include a patient representative in the steering committee. Unfortunately, we did not succeed in doing this. We believe that prior to the forthcoming study, it would be of great value to find out what stroke patients find important to research. Therefore, we would like to send out a questionnaire to anyone who participated and ask which issues should be prioritised in the future. We have referred to a study in the UK(1) where patients, relatives and staff are asked to state the 10 most important priorities. Based on this, we have created a questionnaire in which we now want the patients to rank the various topics. The questionnaire comprises one page and takes about five minutes to answer. We think that it should be sent out about 7 months into the study and be answered completely anonymously. We will not send out any reminders. Before we send out the survey, we check that the patient is alive.

We do not believe that they should be a significant burden for the individuals. The questionnaire will be returned in a prepaid envelope. The next page illustrates the questionnaire.

A fee of SEK 2,000 with the reference *Amendment 7 EFFECTS/Lundström* has been paid.



Erik Lundström  
Chief Investigator EFFECTS

Appendices:

Copies of Resource Certificate for new centre  
EFFECTS Protocol version 5 0 EU-nr\_2011-006130-16

Reference

1. Pollock A, St George B, Fenton M, Firkins L. Top 10 Research Priorities Relating to Life after Stroke – Consensus from Stroke Survivors, Caregivers, and Health Professionals. *Int J Stroke*. 1 April 2014;9(3):313–20.

## Future research areas within stroke

We would like to know the three areas that you feel are most important for us to research in the future. Rank the following areas from 1 to 3, where 1 is what you consider to be most important based on your situation, 2 is the second most important and 3 is the third most important area. You can send the questionnaire back to us in the prepaid envelope. Your answers will be treated completely confidentially and it will not be possible to see what answer you specifically have given. We will not send out any reminders.

Thank you for participating in the EFFECTS study,



Erik Lundström Chief

Investigator for EFFECTS

Associate Professor and Senior Consultant in Neurology

Your ranking	Research area
	How can patients and relatives be helped to accept the long-term consequences of a stroke?
	How can patients be helped to recover from speech difficulties after a stroke?
	How can balance, walking and movement ability be improved after a stroke?
	How can the function of a person's arms and legs be improved/regained after a stroke?
	How can cognition (mental processes) be improved after a stroke? (Mental processes = brain function for processing information and using new knowledge. Functions include processes that require mental ability, such as attention, the ability to interpret, learning, memory, understanding, judgment and decision making.)
	How can vision problems be improved after a stroke?
	How can stroke patients and relatives be helped to handle speech problems after a stroke?
	How can patient self-confidence be improved after a stroke?
	How can fatigue be improved after a stroke?
	Are exercise and physical training programmes good for improving functional ability and quality of life after a stroke, and to avoid further stroke?
	Another area? _____