Karolinska Institutet

Regional Ethical Review Board in Stockholm

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Department of Clinical Neuroscience

Karolinska University Hospital, Solna Neurology,
R3:04 Erik Lundström
Doctor of Medicine, Section Consultant

Regional Ethical Review Board in Stockholm
Karolinska Institutet
171 77 Stockholm

Amendment 4 for the EFFECTS study.

Re.: EFFECTS ESTABLISHING THE EFFECTS(S) AND SAFETY OF FLUOXETINE INITIATED IN THE ACUTE PHASE OF STROKE

Main application: Ref.: 2013/1265-31/2. Date 30 September 2013
Amendment 1: Date: 15 April 2015
Amendment 2: Ref.: 2015/991-32. Date 10 June 2015
Amendment 3: Ref.: 2015/2056-32. Date 30 November 2015

A: As an addition to the previously approved application, resource letters are submitted for:

1. Sahlgrenska Hospital, Gothenburg
2. Högsbo Hospital, Gothenburg
3. Stora Sköndal
4. Östersund Hospital
5. Alingsås Hospital
6. Ängelholm Hospital
7. Stockholm Nursing Home
8. Skåne University Hospital, Lund
9. Örebro University Hospital

We intend to submit resource letters, provided that we have carried out the process described in accordance with point B below, i.e. provided that they meet the requirements for participation in EFFECTS, for Norra Älvsborg County Hospital, Östra Hospital, Sunderby Hospital, Skellefteå General Hospital, Karlstad Central Hospital, Södertälje Hospital, Västmanland Hospital Västerås, Kullbergska Hospital, Ryhov County Hospital Jönköping, Blekinge Hospital Karlshamn, Blekinge Hospital Karlskrona, Kalmar County Hospital, Halland Hospital, Varberg, Södra Älvsborg Hospital, Bromma Geriatric Clinic and

Kungshomen Geriatric Clinic.

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Malmö, Sweden: 20170920

We have previously submitted resource letters for: Danderyd Hospital, Karolinska Hospital (Solna), Hässleholm, Skaraborg Hospital Skövde, Uppsala University Hospital, Karolinska Hospital (Huddinge), Capio St Göran's Hospital, Mora General Hospital, Falu General Hospital, Skaraborg Hospital Lidköping, Norrtälje General Hospital, Kristianstad Central Hospital, Rehab Station Stockholm, Mälar Hospital Eskilstuna, Halland Hospital Halmstad, Skåne University Hospital Malmö, Helsingborg General Hospital, Norrland University Hospital Umeå, Visby General Hospital and Sundsvall Hospital.

B. Explanation of the process for starting new centres – what is required for inclusion in EFFECTS

1. We provide information about the study during an initiation meeting at the clinic in question. Each initiation meeting takes around 3 hours, and is carried out in situ by the Chief Investigator and the Trial Manager. During this meeting, we go through the Study Protocol, CRF, safety reporting (SUSAR, SAE and AE reporting), pharmaceutical management and practical management including randomisation and follow-up. A signed *Center Eligibility* form is then obtained from the investigator (on which the investigator undertakes responsibility for the study), as well as a resource letter (signed by the operational manager), and a financial agreement is drawn up.

2. Every person participating (physicians, nurses) is given delegation by the Principal Investigator (PI) and is added to the delegation list. Signed and dated CVs and certification of completed GCP courses are obtained for all those participating. The complete Investigator Site File and other study documents are handed over during the initiation meeting. The PI signs the protocol and the delegation list.

3. The centre is then activated, and the pharmaceuticals are sent out. By 'activate', we mean that the authorised person receives log-in details for the randomisation system and for the electronic CRF, and is thereby approved to randomise patients in the study.

Once points 1 to 3 above are complete, and once our overall assessment is that the centre is ready to be included in the study, resource letters are sent on an ongoing basis to the Ethical Review Board.

A fee of SEK 2,000 has been paid via Karolinska Institutet. We have stated the reference *Amendment 4 EFFECTS/Erik Lundström*

Solna, 7 June 2016

[signed]
Erik Lundström
Chief Investigator EFFECTS

APPROVED 14 June 2016

[signed]
Pär Sparén
Scientific secretary
Regional Ethical Review Board in Stockholm