



EFFECTS Efficacy of Fluoxetine – a randomisEd Controlled Trial in Stroke

Guide för randomisering av patient och läkemedel i EFFECTS

Version 1.1, 2014-11-07, Erik Lundström



EFFECTS Efficacy of Fluoxetine – a randomisEd Controlled Trial in Stroke

Innan du randomiserar på webben måste du fylla i randomiseringsformuläret på papper.

Det är detta papper som är källdata



EFFECTS Efficacy of Fluoxetine – a randomisEd Controlled Trial in Stroke

[Om sidan](#)

[Om EFFECTS](#)

[Utbildning](#)

[Code Break](#)

[Login](#)

1



Login

2

Här kommer du att kunna logga in till randomiseringssystemet inom kort.

3

Klicka [här](#) för att logga in till prövarmiljön för randomisering.

1. Gå in på hemsidan www.effects.se, välj [Login](#) ur menyn
2. Klicka på [EFFECTS login randomisering](#)

Innan inloggning ska du fylla i uppgifterna på papper. Det underlättar inmatningen och papper utgör källdata.



Neurosciences - Effects - DEVELOPMENT SYSTEM

11 September 2014

Main Menu

- » Introduction
- » Contact Us
- » Login

Introduction

Welcome to the EFFECTS web portal.

Please select LOGIN from the navigation bar, on the lefthand menu, to continue using this site.

- Länkas vidare till annan hemsida
- Klicka på Login



Neurosciences - Effects - DEVELOPMENT SYSTEM

11 September 2014

Main Menu

- » Introduction
- » Contact us
- » Login

Please login to continue using this system.

Username/Email

Password

Login

Note: If you have forgotten your login details, please [click here](#)

- Logga in med din e-post och användarnamn
- Sidan är på engelska



11 September 2014

Main Menu

- » Introduction
- » Contact us
- » Logout

MyActions **1**

- » Tasks

Account Actions **2**

- » Change Password

Management

- » Centres

Welcome Erik Lundstrom

Please select an item from the menu on the left to continue. Or click on any outstanding notifications above.

If you are a PI at centre in the system you will need to create the user accounts for members of staff on your delegation log. In order to do this you should:

- Complete all assigned training as instructed by visiting the 'My Assessments' link in the menu to the left
- Click on the 'Tasks' link in the menu to the left.
- Click on the centre name or number that you wish to add a member of staff to.
- Click the link for 'User Management' from the list of options available.
- Click the 'Add a new User' link.
- Complete the form as required and assign the necessary rights to the user.
- The user should then receive a message to the email address you registered them to with instructions that they need to follow.

- Dina rättigheter avgör hur sidan ser ut
- För att randomisera måste du först välja Tasks (1)
- Vi rekommenderar att du byter lösenord (2)

My Centres

List of the centres that you can view:

1 CentreId	2 Centre Name	3 City	Country	4 Status	5 Permissions
1	Danderyd Hospital	Stockholm	Sweden	Ready	Write
2	Karolinska University Hospital	Solna	Sweden	Ready	Write

För musen över CentreID numret och klicka

1. CentreID är den unika siffra som varje center har
2. Centre Name = Namnet på sjukhuset
3. City = Ort
4. Status = Anger hur långt centret kommit i startprocessen. Start-up: Påbörjat processen, Ready: klara för att randomisera, Suspended: uteslutna
5. Permission: vilken rättighet du har på ditt center

Options

List of the options that you can use for this centre:

Options

Enter data for existing patients
Randomise New Patient
User Management
Drug Stock Management
Centre Management

- Klicka på Randomise New Patient
- OBS! Du måste fylla i pappersformuläret för randomiseringen innan du gör detta

1. Is Patient Eligible?

1 Inclusion Criteria Click arrow to expand/collapse

- Age \geq 18 years
- Clinical diagnosis of stroke 2-15 days previously (Day of stroke onset = Day 0 – randomise on Day 2-15).
- Brain imaging consistent with intracerebral haemorrhage or ischaemic stroke. A normal CT is compatible with a diagnosis of ischaemic stroke.
- Persisting focal neurological deficit is present at the time of randomisation severe enough to warrant treatment from the patient's or carer's perspective.
- Is the patient willing to take tablets for 6 months to help recovery?
- Informed consent can only be obtained from a patient who according to the trial investigator is mentally capable of decision-making and who, after having received information and got answers to their questions, wants to participate in the trial.

2 Exclusion Criteria Click arrow to expand/collapse

- Subarachnoid haemorrhage (unless secondary to intracerebral haemorrhage)
- Unlikely to be available for follow-up for the next 12 months e.g. no fixed home address
- Unable to speak Swedish AND no close family member available to help with follow up forms
- Other life threatening illness (e.g. advanced cancer) that will make 12-month survival unlikely
- History of epileptic seizures
- History of allergy to Fluoxetine
- Contraindications to Fluoxetine including:
 - hepatic impairment (ALAT > 3 upper normal limit)
 - renal impairment (Kreatinin >180 micromol/l)
- Pregnant or breast-feeding, women of child bearing age not taking contraception. Minimum contraception is an oral contraceptive. An HCG-test is to be made prior randomization and after the end of trial medication
- Previous drug overdose or attempted suicide?
- Current or recent (within the last month) depression requiring treatment with an SSRI (selective serotonin reuptake inhibitor) antidepressant
- Current use, or during the last 5 weeks, of a monoamine oxidase inhibitor (MAOI) (e.g. selegiline), or current use of any other medications which have serious interaction with Fluoxetine (e.g. pimozide, Johannesört)
- Currently participating in another trial of a medicinal product (CTIMP)(e.g. SOS, ENOS, DARS)

Name of Randomising Doctor (who confirmed eligibility & obtained consent:)

3

1. Inklusionskriterier. Du behöver inte göra något val
2. Exklusionskriterier: Du behöver inte göra något val
3. Randomiserande doktor: Välj rätt doktor ur menyn

Is the patient currently a hospital inpatient?:

[\(click to clear response\)](#)

If yes what ward are they on?:

1

Yes No

2. Consent

Which version of the patient information leaflet was used?:

Traditional

Has written informed consent been obtained?:

[\(click to clear response\)](#)

Date consent obtained:

2

Yes No

 / / [dd/mm/yyyy]

Who gave consent?:

3

Patient

Have you FAXED that consent is obtained to 08 755 59 51?:

[\(click to clear response\)](#)

Yes No (If no please fax this now)


4

<<

>>

1. Ange om fortfarande på sjukhus
2. Ett absolut krav är skriftligt medgivande av patienten
3. Faxa detta till Danderyds sjukhus. OBS. Du kan klicka i Yes här direkt, eftersom randomiseringssystemet genererar en pdf-fil som du kan skriva ut när randomiseringen är avklarad
4. Klicka på högerpilen för att gå vidare

Name of Randomising Doctor (who confirmed eligibility and obtained consent:)

Please select 

Is the patient currently a hospital inpatient?:

[\(click to clear response\)](#)

Yes No

If yes what ward are they on?:

2. Consent

Which version of the patient information leaflet was used?:

Traditional

Has written informed consent been obtained?:

[\(click to clear response\)](#)

Yes No

Date consent obtained:

/ / [dd/mm/yyyy]

Who gave consent?:

Patient


Have you FAXED that consent is obtained to 08 755 59 51?:

[\(click to clear response\)](#)

Yes No (If no please fax this now)

<<

>>

Please check all missing or incorrect data items 

- Om du missar att fylla i någon del så markerats den som röd och du uppmanas att fylla i något som saknas eller kontrollera om det är inkorrekt ifyllt. Det går inte att gå vidare med felaktig inmatning.

Name of Randomising Doctor (who confirmed eligibility and obtained consent:)

Anders Andersson ▾

1

Is the patient currently a hospital inpatient?:

[\(click to clear response\)](#)

Yes No

If yes what ward are they on?:

R15

2. Consent

Which version of the patient information leaflet was used?:

2

Traditional

Has written informed consent been obtained?:

[\(click to clear response\)](#)

Yes No

Date consent obtained:

10 / 09 / 2014 [dd/mm/yyyy]

Who gave consent?:

3

Patient

Have you FAXED that consent is obtained to 08 755 59 51?:

[\(click to clear response\)](#)

Yes No (If no please fax this now)

<<

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1. Meningen "click to clear response" nollställer det aktuella valet och du kan välja ett annat svar
2. Consent (medgivande) kan i svensk lagstiftning endast fås genom att patienten skriver under. Därför är "Traditional" förvalt
3. Det samma gäller den andra förvalet "Patient"

Name of Randomising Doctor (who confirmed eligibility and obtained consent:)

Anders Andersson ▾

Is the patient currently a hospital inpatient?:

[\(click to clear response\)](#)

Yes No

If yes what ward are they on?:

R15

2. Consent

Which version of the patient information leaflet was used?:

Traditional

Has written informed consent been obtained?:

[\(click to clear response\)](#)

Yes No

Date consent obtained:

10 / 09 / 2014 [dd/mm/yyyy]

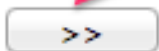
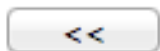
Who gave consent?:

Patient

Have you FAXED that consent is obtained to 08 755 59 51?:

[\(click to clear response\)](#)

Yes No (If no please fax this now)



- När du har fyllt i alla val klickar du vidare på högerpilen

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 3)

<< >>

3. Patient details

Patient's Forename:

Family name:

Gender: Male Female
[\(click to clear response\)](#)

Date of Birth: / / [dd/mm/yyyy]

Ethnicity: White Asian Black Chinese Other
[\(click to clear response\)](#)

Please specify:

Marital Status: Married Single Widowed Separated/Divorced Partner Other
[\(click to clear response\)](#)

Living Arrangements: Living alone Living with someone else Institutional living Other
[\(click to clear response\)](#)

Employment: Full time Part time Voluntary Retired Unemployed or disabled Other
[\(click to clear response\)](#)

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- Randomiseringen på webben följer samma ordning som pappersdokumentet
- Notera att datumet anges i dag (2 siffror), månad (2 siffror) och år (fyra siffror)

Prövmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 4)

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4. Co-morbidities (based on patients report and medical notes)

- i. Depression (requiring antidepressants or referral to psychiatrist/psychologist):
- a. Previous depression?: Yes No Unknown
(click to clear response)
- b. Current depression?: Yes No Unknown
(click to clear response)
- ii. History of Diabetes?: Yes No Unknown
(click to clear response)
- iii. Previous Coronary Heart Disease (i.e. definite angina, MI, CABG, coronary stenting): Yes No Unknown
(click to clear response)
- iv. Previous ischaemic stroke/TIA or stroke of uncertain pathology (before this event): Yes No Unknown
(click to clear response)
- v. Previous Intracranial bleeding (including prior haemorrhagic stroke or subdural): Yes No Unknown
(click to clear response)
- vi. Past history of upper gastrointestinal bleeding: Yes No Unknown
(click to clear response)
- vii. Current or past Hyponatraemia (Na <130mmol/l): Yes No Unknown
(click to clear response)
- viii. Bone Fractures: Yes No Unknown
(click to clear response)

- Du kan hela tiden navigera fram och tillbaka på hemsidan med de olika pilarna (rektangel)

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 5)

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5. CURRENT MEDICATIONS

	Drug Name	Drug Type	Action
e.g.	Phenytoin	Anti-convulsant	
	<input type="text"/>		<input type="button" value="Add"/>

Note: To add a new medication, please enter medication name and then click 'Add'.

Note: If the medication is not showing up in the pop up list continue writing until the name is complete as the list only contains drugs of interest but we require information about all of the medications that is on.

Note: To delete a medication, please select the line by clicking on the radio button on the left and then click 'Delete'.

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- Ange läkemedel (Namn eller generika)
- Du behöver inte ange doseringen
- Vi vill varna för kontraindikationer eller interaktioner

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 5)

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5. CURRENT MEDICATIONS

Drug Name	Drug Type	Action
e.g. Phenytoin	Anti-convulsant	
<input type="text" value="Tegr"/>		<input type="button" value="Add"/>

Note: To add a new medication, click on the radio button on the left and then click 'Add'.
Note: If the medication is on the list, click on the radio button on the right and then click 'Delete'.
Note: To delete a medication, click on the radio button on the left and then click 'Delete'.

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1. Det räcker med att du börjar skriva ett läkemedel så kommer förslag på namn upp
2. Klicka på "Add" för att lägga till läkemedlet
3. När du har skrivit in ett läkemedel är det inte alltid synligt i rutan (det är en bugg i systemet), arbete pågår för att ordna detta.

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 5)

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5. CURRENT MEDICATIONS

Drug Name	Drug Type	Action
e.g. Phenytoin	Anti-convulsant	
<input type="radio"/> Tegretol - Karbamazepin	Anti-convulsant	Delete
<input type="text"/>		Add

Note: To add a new medication, please enter medication name and then click 'Add'.

Note: If the medication is not showing up in the pop up list continue writing until the name is complete as the list only contains drugs of interest but we require information about all of the medications the patient is on.

Note: To delete a medication, please select the line by clicking on the radio button on the left and then click 'Delete'.

This patient is taking an anticonvulsant - [if this is for epilepsy the patient is not eligible for enrollment in EFFECTS](#). If it is prescribed for another reason e.g. pain, then the patient is eligible.
Has the patient a history of epilepsy?:
([click to clear response](#)) Yes No

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- Om du t.ex. anger Tegretol kommer det upp en varning: Du får inte inkludera om patienten har epilepsi. Men det går bra om Tegretol förskrivs för annan indikation (t.ex. neuropatisk smärta) (rektangel)

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 6)

6. INFORMATION ABOUT THIS STROKE

Date of Stroke onset:

(if date of onset uncertain-please give date when patient last known to be free from stroke symptoms)

 / / [dd/mm/yyyy]**National Institute of Health Stroke Score (NIHSS)**

1.
 - a. Level of Consciousness(LOC): (0-3)
 - b. LOC Questions: (0-2)
 - c. LOC Commands: (0-2)
2. Best Gaze: (0-2)
3. Visual Field testing: (0-3)
4. Facial Paresis: (0-3)
5. Motor function – Arm: RIGHT (0-4, U=Untestable)
Motor function – Arm: LEFT (0-4, U=Untestable)
6. Motor function – Leg: RIGHT (0-4, U=Untestable)
Motor function – Leg: LEFT (0-4, U=Untestable)

- Du fyller i datum för strokeinsjuknande och NIHSS

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Sections 7,8 & 9)

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7 . FUNCTIONAL STATUS BEFORE THIS STROKE

Did the patient require assistance from anyone to undertake activities of daily living (e.g. walking, showering, dressing, feeding, toileting)?:
(click to clear response) Yes No

8. FUNCTIONAL STATUS NOW

Able to lift both arms off the bed?:
(click to clear response) Yes No

Able to walk (even with a walking aid) but without the help of another person?:
(click to clear response) Yes No

9. PATIENT'S CURRENT MOOD (Patient Health Questionnaire-2)

Over the past 2 weeks, has the patient often been bothered by:

- i. Little interest or pleasure in doing things?:
(click to clear response) Yes No Unknown
- ii. Feeling down, depressed, or hopeless?:
(click to clear response) Yes No Unknown

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- Svarar på några ytterligare frågor om hälsotillståndet

Prövarmiljö

10. TYPE OF STROKE

Does brain scan show recent intracerebral bleeding?:

[\(click to clear response\)](#)

1

Yes No

If yes is the bleeding likely to be due to haemorrhagic transformation of an infarct?:

[\(click to clear response\)](#)

Yes No

If Ischaemic or Ischaemic with haemorrhagic transformation please complete Stroke Classification & Cause sections

1. Ischemisk stroke klassificeras på två sätt. Ruta 1: ischemi/blödning

The pattern of neurological deficit (*tick one box on each line*)

1 Unilateral weakness (and/or sensory deficit) affecting face?

[\(click to clear response\)](#)

2

Yes No Unknown

2 Unilateral weakness (and/or sensory deficit) affecting arm or hand?

[\(click to clear response\)](#)

Yes No Unknown

3 Unilateral weakness (and/or sensory deficit) affecting leg or foot?

[\(click to clear response\)](#)

Yes No Unknown

4 Dysphasia?

[\(click to clear response\)](#)

Yes No Unknown

5 Homonymous hemianopia?

[\(click to clear response\)](#)

Yes No Unknown

6 Visuospatial disorder (e.g. sensory or visual inattention, unable to copy pictures)?

[\(click to clear response\)](#)

Yes No Unknown

7 Brainstem or cerebellar signs (e.g. nystagmus or ataxia)

[\(click to clear response\)](#)

Yes No Unknown

8 Other neurological deficit?

[\(click to clear response\)](#)

Yes No Unknown

What is the most likely **cause of the Ischaemic stroke** (*please tick most likely*):

[\(click to clear response\)](#)

3

Large artery disease (cortical stroke (TACS/PACS +carotid atheroma >50% with no other cause)

Small vessel disease (Lacunar Stroke without carotid atheroma or cardiac source)

Embolism from the heart (e.g. Atrial Fibrillation, prosthetic valve, endocarditis)

Another cause (e.g. dissection, illicit drugs)

2. Klassificering av ischemisk stroke enligt Oxfordshire Community Stroke Project (OSCP) Classification genom att svara på 8 frågor. Ruta 2

3. Klassificering enligt TOAST-kriterier. Punkt 3

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v1.2 (Section 11)

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11. CONTACT DETAILS PATIENT'S CONTACT DETAILS TO ALLOW CENTRAL FOLLOW UP

Street name	<input type="text" value="Kungsgatan"/>
Street no.	<input type="text" value="28"/>
Town/City	<input type="text" value="Stockholm"/>
Postcode(no spaces):	<input type="text" value="12333"/>
Tel No.:	
Landline(no spaces)	<input type="text" value="08898989"/>
Work(no spaces)	<input type="text"/>
Mobile(no spaces)	<input type="text"/>

OTHER POSSIBLE CONTACTS (Family members or close friends who may be contacted if we can't contact the patient.)

	Name	Relationship	Tel No.(no spaces)
1.	<input type="text" value="Arne Andersson"/>	<input type="text" value="Husband"/>	Home: <input type="text"/>
			Work: <input type="text"/>
			Mobile: <input type="text"/>

- Kontaktuppgifter patient. Obs postnr och telefonnr måste anges i en följd utan mellanrum
- Minst en kontaktperson måste anges

Prövarmiljö

GENERAL PRACTITIONERS CONTACT DETAILS

GP Name (if available):

Dr:

Practice Name:

Street name

Town/City

Postcode(no spaces):

Tel No.(no spaces):

FAX No.(if available, no spaces):

- Det finns möjlighet att ange namn på distriktsläkare. Ej obligatorisk uppgift

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 Overview

<<

Submit

EFFECTS Enrollment - Randomisation Form Basic Information

Effects study number:
Centre name: Malmö Hospital
Treatment ID at randomisation:
Date of randomisation: 25/09/2014 21:29:54
User who randomised:
Date/time this form was accessed:

EFFECTS Enrollment - Randomisation Form (Section 1 & 2)

1. Is Patient Eligible? Yes
Name of randomising Doctor (who confirmed eligibility and obtained consent): Anders Andersson

Is the patient currently a hospital inpatient?: Yes
If yes what ward are they on?: R15

2. Consent

Which version of the patient information leaflet was used?: *
Has written informed consent been obtained?: Yes
Date consent obtained: 25/09/2014 [dd/mm/yyyy]
Who gave consent?: *
Have you FAXed that consent is obtained to 08 755 59 51? (if 'No') Yes

- Översikt och möjlighet att granska alla inmatade uppgifter
- Klicka på Submit om allt stämmer

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 11)

PATIENT SUCCESSFULLY RANDOMISED!

EFFECTS trial ID No.: 0030

Treatment ID: 5065

[> See dispensing confirmation form](#)

Minimisation counts for each demographic in here

Session('delay') this is the Delay from stroke onset to randomisation

Session('progindex') this is the Predicted probability of a good outcome

Session('motor_defecit') this is the outcome of earlier questions to do with motor function

Session('aphasia') this is the outcome of earlier questions to do with speech function

Session('Allocation') this is treatment allocation for the patient, this can change due to stock levels

<===== Current Patient Information - Can't talk or confused overview =====>

NIHSS 1b.= 0

NIHSS 1c.= 1

NIHSS 9. = 0

NIHSS 10.= 0

Final Can't talk result= N

<===== Current Patient Information - Motor Deficit Overview =====>

NIHSS 5= 1

- Varje patient erhåller två unika nummer
- EFFECTS trial ID No = unikt nummer för patienten
- Treatment ID = unikt nummer för läkemedel

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 11)

PATIENT SUCCESSFULLY RANDOMISED!

EFFECTS trial ID No.: 0030

Treatment ID: 5065

[> See dispensing confirmation form](#)

Minimisation counts for each demographic in here

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Session('Allocation') this is treatment allocation for the patient, this can change due to stock levels

<===== Current Patient Information - Can't talk or confused overview =====>

NIHSS 1b.= 0

NIHSS 1c.= 1

NIHSS 9. = 0

NIHSS 10.= 0

Final Can't talk result= N

<===== Current Patient Information - Motor Deficit Overview =====>

NIHSS 5= 1

- Övrigt data på sidan: Underlag för minimisation etc.

Prövarmiljö

EFFECTS Enrollment - Randomisation Form v4.3 2014-09-09 (Section 11)

PATIENT SUCCESSFULLY RANDOMISED!

EFFECTS trial ID No.: 0030

Treatment ID: 5065

[> See dispensing confirmation form](#)



Minimisation counts for each demographic in here

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Session('Allocation') this is treatment allocation for the patient, this can change due to stock levels

<===== Current Patient Information - Can't talk or confused overview =====>

NIHSS 1b.= 0

NIHSS 1c.= 1

NIHSS 9. = 0

NIHSS 10.= 0

Final Can't talk result= N

<===== Current Patient Information - Motor Deficit Overview =====>

NIHSS 5= 4

- Klicka på "See dispensing confirmation form"

Prövarmiljö



Dispensing Confirmation FAX

Anna Andersson 10/09/1945 28 Kungsgatan Stockholm who is an inpatient on ward R15 was enrolled into the EFFECTS trial on 25/09/2014 21:43:36

Their EFFECTS trial ID No. is: 0030

The patient treatment pack allocated to this patient is: 5065

Instructions for trial staff

Please print 2 copies of this form. Place 1 copy (without the label/flag) in the patient's CRF and fax 1 copy to the main centre.

Please ensure that the trial treatment is started as soon as possible.

To confirm that the EFFECTS trial treatment has been dispensed remove the adhesive Treatment No. label/flag from the treatment pack and stick it in the box below

- Förifylld pdf-fil som ska faxas till Danderyd

EFFECTS TRIAL DEVELOPMENT - Patient recruited



Inkorgen ✕



 effects.notifications@ed.ac.uk

22:43 (5 minuter sedan) ☆



till mig, c.mcgill, anders ▾



engelska ▾



svenska ▾

Översätt meddelande

Inaktivera för: engelska ✕

Automatic Message from EFFECTS

Patient 0030 has been recruited into the EFFECTS study. Below is the first treatment pack ID for this patient.

Effects trial patient ID: 0030

Treatment pack ID at randomisation: 5065

Centre recruited to: 1

Please visit this link to log into the EFFECTS web portal to view further information about this patient. URL:

<http://dcnapp1.dcn.ed.ac.uk/Effects.dev/>

Web registration completed by Erik Lundstrom on 25/09/2014

- Automatiskt mejl till co-chief och trial manager för EFFECTS samt principal investigator vid varje center

Prövarmiljö